EXHIBIT H

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION

MASTER FILE NO. 2:12-MD-02327

MDL NO. 2327

GENERAL CAUSATION RE: PROLIFT and PROLIFT+M

PURSUANT TO NOTICE, the deposition of BRIAN FLYNN, M.D. was taken on behalf of the Plaintiff at Denver Marriott West, 1717 Denver West Boulevard, Golden, Colorado, on April 14, 2016, at 11:52 a.m., before Melanie L. Giamarco, Registered Merit Reporter, Certified Realtime Reporter, and Notary Public within Colorado.

GOLKOW TECHNOLOGIES

877.370.3377 ph/ 917.591.5672 fax

deps@golkow.com

A P P E A R A N C E S

For the Plaintiffs:
GREG BENTLEY, ESQ.
SHEA SHAVER, ESQ
ZONIES LAW, LLC
1900 Wazee Street
Suite 203
Denver, Colorado 80202

For the Defendants Johnson & Johnson and Ethicon:
BARRY J. KOOPMANN, ESQ.
DAVID J. DUKE, ESQ.
BOWMAN AND BROOKE, LLP
150 South Fifth Street
Suite 3000
Minneapolis, Minnesota 55402

I N D E X

EXHIBITS

EXHIBITS (Continued)

BRIAN FLYNN, M.D.,
after having been duly sworn, was examined and testified as follows:

P R O C E E D I N G S

EXAMINATION

BY MR. BENTLEY:

Q. Good morning, Doctor. My name is Greg Bentley. We previously met. We just completed your TVT-O deposition, and we're now moving into the general causation deposition regarding Prolift. Do you understand that?

A. I do.

Q. Okay. And I represent the plaintiffs in the MDL; do you understand that?

A. Yes.

Q. Doctor, we previously entered some exhibits today for the TVT-O deposition, and now we are starting the Prolift portion.

You brought a couple of flash drives previously. Are those the same flash drives that are applicable to this deposition regarding Prolift?

A. Yes.

Q. You don't have any additional flash

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drives for this deposition?
A. I don't have any additional flash drives. I do have an additional CD and a few other invoices that are specific to this deposition.
Q. Okay. And you also brought some binders with what appears to be -- or could you tell me what are in the binders?
A. I have three binders, one is for Prolift, and the other two are for Prolift+M.
Q. Okay. And you brought a CD. Do you have an understanding of what's on that CD?
A. It's some Prolift and -- Prolift studies and pelvic organ prolapse studies. And I have that CD here.
Q. Are those studies that are in addition to what was on the flash drives, or just --
A. I think it repeats. I believe these studies are also on the flash drive. But just for completeness, in case they were not, I brought the CD.
Q. Do you have an understanding of when that CD was made?
A. It was sent to me -- I received it on July 29th, 2015.
Q. And then I have in front of me a

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one-page invoice. Do you have any other invoices for the Prolift and Prolift+M?
A. That's the Prolift+M invoice, and then I have two invoices on Prolift.
Q. Okay. This was inside one of the binders. I'll start with the Prolift invoice, if you don't mind.
MR. BENTLEY: We're going to mark this as Exhibit 1.
(Exhibit 1 was marked for identification.)
Q. (By Mr. Bentley) And it looks like you spent 21 hours preparing your Prolift report; is that correct?
A. Well, there's two --
Q. Oh, there's two, I'm sorry.
MR. BENTLEY: We'll mark the -- so for the record, we'll mark the one that's dated July 1 to August 31, 2015, as Exhibit 1. And we're going to mark the second invoice dated September 1 to October 2, 2015, as Exhibit 2.
(Exhibit 2 was marked for identification.)
Q. (By Mr. Bentley) So on Exhibit 1, you list 21 hours of preparation for the Prolift report, and on Exhibit 2, you list 12 hours.
So you spent approximately 33 hours

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preparing your Prolift report; do you agree with that?
A. I do.
Q. And then on Exhibit 1, you have a telephone conference of 1.25 hours and a four-person, right, in-person conference for four hours, so five and a quarter plus 33, so we have 38 and a quarter hours in total preparation; would you agree with that? Do the math.
A. I agree with that.
Q. Okay. And the last date you have on Exhibit 2 is October 2, 2015. Subsequent to that date, have you done any work on Prolift?
A. Very little. Most of the work was done in preparation of this report for a case in the fall, and then before I submitted this this year in 2016, I went through the final draft and signed it on February 26, so there was some very minor editing after those dates.
Q. This doesn't include your time at trial for the Prolift, correct?
A. It doesn't include the time here at trial.
Q. Okay. And you just testified that you don't believe you made any substantive edits to the

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report since the previous report?
A. That's correct.
Q. After October of 2015, have you continued to stay up to date on the medical literature regarding prolapse and Prolift?
A. Yes.
Q. Have you reviewed any new articles specific to Prolift?
A. There may be a few articles. And they would all be included in my reliance list and on my references on this report.
Q. Okay. So that was my next question, was, if we compared the reliance list from your previous report to this one, that would identify the new articles that you've reviewed for this report?
A. Yeah, there may be a few other things that don't appear here, but for the most part, it's comprehensive.
Q. Among those potentially few other things, was there anything that was important to you that you would like to add to your reliance list at this point?
A. I've reviewed a number of depositions recently, so I'm not certain if -- I'm looking at

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the expert report list here, so there'd be some depositions in addition to these reports that I've looked at.

Q. And what depositions have you reviewed?

A. I've looked at a report from Dr. Ostergard, Dr. Blaivas and Dr. Elliot. I've looked at a number of reports from Doctors Rosenzweig and Margolis, so it's hard for me to know if -- which reports or which depositions because they're from multiple cases, but there may be one from Rosenzweig or from Margolis.

Q. And how did you decide to review those specific depositions?

A. They were sent to me by Ethicon counsel.

Q. Did you request to review any other depositions?

A. No, I did not.

Q. Have you ever requested to review, say, internal corporate depositions from Ethicon?

A. No, I have not.

Q. Did these 38 and a quarter hours include any preparation for the Prolift+M at the same time you were doing Prolift?

MR. KOOPMANN: Object to form.

A. There's a separate invoice for +M.

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There's some carryover from the Prolift report to the +M, so there's a lot less hours on the +M, so it would depend on how you want to characterize that. But, you know, the +M report took me a lot less time because I had recently completed the Prolift report.

Q. And have you previously been deposed on Prolift?

A. I never have been on either of these products.

Q. Have you ever been deposed on a product that's used to treat prolapse?

A. No, not as an expert. I have as a treating physician.

Q. Now, you submitted your Prolift on February -- strike that.

You signed your Prolift report on February 26, 2016; is that correct?

A. Yes, that's correct.

Q. And did you write that report yourself?

A. I did.

Q. Did you receive any assistance in writing that?

MR. KOOPMANN: Object to form.

I'm going to instruct you not to answer that

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question. That calls for work-product information.

Q. (By Mr. Bentley) Did you physically type the words that are in your report that's dated February 26, 2016?

A. I did.

Q. No one else typed any words for you?

MR. KOOPMANN: Object to form. Instruct the witness not to answer the question.

Q. (By Mr. Bentley) Did you copy and paste any section of this report?

A. As I mentioned earlier, the Prolift report did carry over into the +M report, so yes, for the Prolift+M report.

Q. So aside from the Prolift and the Prolift+M report, was any of this content copied from some other source?

A. Not that I'm aware of.

Q. When you submitted your report, you also submitted a reliance list. Are those materials you relied upon in reaching your opinions here?

A. Yes.

Q. Now, it's fairly extensive. Do you think that you actually reviewed every one of those materials on that list?

A. I've at least seen all of them. Some of

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them I've looked at in greater detail than others, but these are articles that I rely on or I may rely on in the future.

Q. Had you reviewed some of these articles prior to writing your report?

A. Yes, quite a few of the articles and quite a few of the PowerPoints and some of the media that was created.

Q. But it's your testimony today that you've reviewed every one of the documents that's listed on this report, or on this list?

MR. KOOPMANN: Object to form.

A. I think this is a comprehensive list. I have looked at all of these articles, some greater than others.

Q. (By Mr. Bentley) On the section titled "Production Materials," there's a number of anatomy videos and instructional videos. Did you watch all of those?

A. I can't say for sure if I watched all of them. I've watched a number of them. I did include those on the USB drive, and so there's quite a bit of media there.

Q. Okay. As we sit here today, is there any way for you to tell me which ones you actually

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reviewed and which ones you didn't?
A. Not easily. Not without having to watch all of them, because they're listed by the Ethicon internal number, and so it's not entitled, so I can't say just by looking at the reliance list.
Q. And how did you come to receive all of these internal Ethicon documents and videos?
A. They were sent to me either electronically by a zip file or on a CD or on a USB.
Q. Did you specifically request any of them?
A. No, I did not.
Q. Are there any documents that you would like to request to see?
A. No.
Q. Do you feel that you've been provided with all the pertinent important documents to reach your opinions in this case?
A. Yes.
Q. So in your report, you have footnotes for a number of different studies; is that correct?
A. Yes.
Q. But I didn't notice any footnotes that cite to an Eth mesh or a production document; is

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that correct?
A. I would have to read the entire report, but let me take a look here. I can submit this as an exhibit, but there's one, two, three, four, five references at the end that don't have a number or a first author, so . . .
Q. And what are those five references?
A. One is the AUA position statement, the AUGS frequently asked questions, the AUGS position statement, Oxford Levels of Evidence for practitioners, and then Sunoco MDS.
Q. Do you have an understanding that all of those are pubicaly available documents and not internal Ethicon documents?
A. Yes, those are all publicly available.
Q. How did you decide which articles to cite -- strike that.
How did you decide which articles and publicly available documents you cited in your report -- how'd you pick which ones to cite to?
A. I try to start with articles that I've read previously that impact my thoughts and opinions and how I practice, ones that are also cited by colleagues, by key opinion leaders, by thought leaders in urology and urogynecology, and

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the ones that I've used to formulate my opinions.
Q. So according to that, did you not use any of the Ethicon production materials to formulate your opinions in this case?
MR. KOOPMANN: Object to form.
Sorry. Go ahead.
A. A lot of the Ethicon documents -- there's quite a bit of overlap with the references, and so some of the Ethicon documents, especially the PowerPoint presentations, are heavily referenced. So there's some overlap there, but I didn't cite that as a unique reference.
Q. (By Mr. Bentley) Did you formulate your opinions prior to reviewing these Ethicon mesh documents?
A. No, they were given to me, provided to me in advance. Some of them I had received over the fall of 2015, and maybe more recently, but I've relied on a number of those in formulating opinions.
Q. And which ones have you specifically relied upon to formulate opinions in your report?
A. When I looked at some of the PowerPoint presentations on biomaterials, I think those PowerPoint presentations have a number of the

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references, for instance, like the Dietz paper, the admid classification, some of the Moally papers that are both referenced in the reliance list and also in the Ethicon prof ed literature.
Q. So is it fair to say you used the Ethicon mesh documents to help direct you to the original citations to go to review to formulate your opinions in this report?
A. It would work in both directions. Many of them I was already familiar with. Some of them I was not familiar with and did become aware of those documents after looking at the prof ed material.
Q. But none of the Eth mesh documents were important enough to add a footnote citation into your report; is that correct?
A. That's not how I would state that.
Q. Did you add footnote citations for documents that were important to you?
A. I did.
Q. And none of those footnotes include Eth mesh docs; isn't that correct?
A. That's correct.
Q. Doctor, did you ask the attorneys who retained you to provide opinions in this case to

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provide you with all the documents that demonstrate Ethicon's knowledge as to complications associated with Prolift?

A. No, I did not.

Q. Would you have liked to have seen documents -- strike that.

If they exist, would you have liked to have seen documents demonstrating Ethicon's internal knowledge of complications associated with Prolift?

A. Some of it was sent to me. I didn't have to ask for it. It's in a lot of those internal documents, including PowerPoint presentations and information that I received from prof ed managers, and so I didn't have to specifically ask for it.

Q. So is it your testimony today that you believe you've received and reviewed all internal documents demonstrating Ethicon's knowledge of complications associated with Prolift?

A. I can't say if I've seen all of it. I don't have any way of knowing what they've sent me. But I know they've sent me a number of documents pertaining to complications.

Q. And that's information you would have liked to have reviewed; is that correct?

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MR. KOOPMANN: Object to form.

A. Yeah, I appreciated reviewing that stuff.

Q. (By Mr. Bentley) I mean, potentially, if there's a document that you didn't see that indicated Ethicon had knowledge about complications associated with Prolift and you didn't review that, if you had seen that, that could have altered your opinions in this case; isn't that true?

MR. KOOPMANN: Object to form.

A. It's potentially true. It's speculative, but maybe.

Q. (By Mr. Bentley) Is it fair to say that your opinions in this case are largely based on your own clinical experience and medical literature you reviewed?

A. Yes.

Q. And is it fair to say that your opinions in this case are not really related to -- strike that.

Is it fair to say that your opinions in this case are not really based on Ethicon's internal knowledge or what Ethicon did or didn't do? Is that a fair statement?

A. It's not fair.

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Q. So which Ethicon documents are you basing your opinions on here?

MR. KOOPMANN: Object to form.

A. As I mentioned earlier, in a number of the PowerPoint presentations during the prof ed events and things that have been shared with me, there's slides on complication data, and so that information was shared when we were preparing for courses and presenting at courses, prof ed courses.

Q. (By Mr. Bentley) So your opinions on this case are based upon complications rates that were provided to you from Ethicon; is that your testimony?

MR. KOOPMANN: Object to form.

A. I received some complication data and some information. How complete that is, I don't -- I can't answer that question.

Q. (By Mr. Bentley) And it wasn't important enough to add a footnote citation into your report; is that true?

A. I feel that I have, you know, enough references here, well over a hundred references. I feel the document's heavily referenced.

Q. I appreciate that, but that wasn't exactly my question, Doctor.

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My question was, the Ethicon internal documents weren't important enough to add a footnote -- strike that.

The Ethicon internal complication rates documents weren't important enough to add a footnote citation into your report; is that true?

MR. KOOPMANN: Object to form.

A. Are you talking about the report or the reliance list?

Q. (By Mr. Bentley) Doctor, you testified that you based your opinions upon some complications data that was provided to you by Ethicon; is that correct?

A. Yes.

Q. Okay. And my question is, that complications data that was provided to you, why was that not cited in your report?

A. My report is basically primarily on my experience and the review of the medical literature.

Q. Thank you.

Doctor, are all of your opinions contained within your report?

A. The overwhelming majority of my opinions. There may be one I missed or overlooked

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that's not in the report, but to the best of my knowledge, yes.

Q. And as you sit here today, you don't have any other opinions that you anticipate providing to the jury at trial; is that correct?

A. Nothing that I anticipate, correct.

Q. Have any of your opinions changed since you wrote your report in February -- strike that.

Have any of your opinions changed since you signed your report in February of this year?

A. That's correct.

Q. And you stand by all of your opinions in that report?

A. I do.

Q. I'd like to explore how you cited to various articles within your report.

Just generally, how did you choose which articles you wanted to cite to in your report?

MR. KOOPMANN: Object to form.

A. So I started out with articles that I was already immediately familiar with, articles that I had used previously in other types of reviews or reports or presentations that I put together, articles that have been important to me long-term over the last 15 years in affecting how I

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think about prolapse and how I manage it, articles that had been provided to me for review by others.

As I drafted the article, there were areas that I felt that I needed to do more research on, and articles would then be added in as I saw gaps in the report. And so it was definitely an evolving process. It happened in stages. Some of these articles I've read years ago and reread them and included them. Other ones are articles that I've become aware of just more recently.

Q. (By Mr. Bentley) Do you agree that there's a large number of articles that exist out in the public domain that are not cited in your report?

A. I agree that there's certainly articles that are not cited in my report. I don't know exactly how many. I'm sure I'm dealing with just a percentage of articles.

Q. Certainly. And there's a number of articles that are -- strike that.

There's a number of scientific articles that are cited in your reliance list that you don't discuss in your report; would you agree with that?

A. I do agree with that, yes.

Q. Okay. So I believe you've testified

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that you decided to include certain articles in your report, but based on which articles you thought were important to you; is that fair?

A. Yes, that's fair.

Q. How did you decide not to include an article in your report?

A. Well, if I had never read it before or no one's ever asked me to read it, that wouldn't be included in it. If I did a PubMed research search and it didn't come up, then I wouldn't have included it, if I felt that it was of low-level evidence, if there were some concerns about the methods of the article. I tried to choose articles that supported my opinions, so it's more what I use to make my opinions, not what I decided not to use.

Q. So did you make a conscious decision not to include articles that didn't support your opinion?

A. Those articles, some of those appear in this report with reference to claims that have been made by plaintiffs and plaintiffs' experts, so those articles are -- many of those are included in this report. So I felt that this was a very balanced report. Naturally, the articles that I rely on to formulate my opinions are going to be

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more heavily emphasized.

Q. And you feel it's important to have an objective or balanced approach to presenting your opinions here?

A. Well, those words kind of are in contradiction of each other, "balanced" and "opinionated." But, you know, I made opinions based on articles that formulated how I practice, how I teach my residents and fellows, how I see colleagues in the medical community practice, what I've witnessed at scientific meetings. So it's a process, but I tried to choose the articles that were most impactful.

Q. You wouldn't want to deliberately just not cite to articles that were contrary to your opinions in this report, would you?

A. There's articles that I'm aware of that I did not cite in this report, whether you want to call that deliberate or not deliberate. Like I mentioned earlier, the articles that I cite are articles that I feel are valuable and supportive of my opinions.

Q. And I believe you mentioned that one way you evaluate the importance of an article is based off of the level of evidence; is that correct?

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A. Yes, that's one way.
Q. Could you please explain what's your understanding of levels of evidence?
A. Yes. And I did reference that. If you look at the levels of evidence for practitioners, you have Level I evidence, which would be the highest level that is systematically used, meta-analyses and RCTs. And then go all the way down to the bottom of the pyramid, Level IV would be, you know, case reports, and so that would be the lowest level of evidence. In between, you have case series, and then prospective studies that are nonrandomized.
Q. Okay. And you wouldn't consider your report a systematic review of the totality of literature that exists regarding Prolift, would you?
A. It's not a systematic review. That's correct.
Q. And likewise, you didn't perform a meta-analysis here, did you?
A. I did not.
Q. In fact, you're here relying upon other people's systematic reviews and meta-analyses; is that correct?

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A. As well as my own personal experience with this device.
Q. Doctor, is one of the bases of your opinions here -- I believe your report states that you're also relying upon your training; is that correct?
A. On my training?
Q. Training.
A. Yes, education, training and clinical practice and experience.
Q. During your medical education and subsequent training, when did you first become exposed to training on Prolift?
A. On Prolift? Well, Prolift I became aware of early in my practice, sometime in around 2003 and 2004. I began clinical practice in 2002 after completing my fellowship. So Prolift was not a product that was commercially available when I was a resident or fellow or medical student.
Q. When you were a resident or fellow, were there any transvaginal mesh kits available for prolapse?
A. Not for prolapse.
Q. Okay. So is it fair to say that the total extent of your training on Prolift was

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provided by Ethicon?
A. No, that's not fair.
Q. Where have you received training specific to Prolift other than through Ethicon?
A. From observing colleagues performing the procedure, from my review of the medical literature. A lot of overlap with Prolift came from other products or maybe from other prolapse procedures, and so Prolift didn't develop or evolve inside a vacuum. It came out of other procedures and devices. So I had extensive knowledge on Gynemesh mesh and Prolene soft mesh well before Prolift. And so that's -- it was a process.
MR. BENTLEY: Okay. I'm going to strike that as nonresponsive.
Q. (By Mr. Bentley) Doctor, my question is, other than training you received from Ethicon, have you received any other training specific to Prolift, formalized training?
MR. KOOPMANN: Object to form.
A. What would you mean by "formalized training"?
Q. (By Mr. Bentley) Well, would you define for me what you consider formal training?
A. Formal training? Well, I would say

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formal training would be something that you received in your residency or in your fellowship, something you received a certificate or document supporting your hours that you trained on the device. So for instance, with prof ed events, people may come away with a certificate.
Formal training is going to be different depending on who you talk to, but once you finish your residency and fellowship, all physicians in practice look for ways of training on new devices, and that can come from professional medical societies, from industry, from colleagues. So that's how I would define "formal training."
Q. Thank you.
Have you received any training specific to Prolift from any of the professional medical societies?
A. I have not.
Q. And you previously testified Prolift nor any of the transvaginal mesh kits for prolapse were available during your residency or fellowship. So other than the training that you've received from Ethicon, have you received any other formal training specific to Prolift?
A. No.

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Q. I believe you testified that you used Gynemesh prior to using the Prolift total repair kit; is that fair?
A. Yes.
Q. Did you receive formalized training from Ethicon on the Gynemesh?
A. No.
Q. Have you used any other total repair kit -- repair mesh kits for prolapse?
A. I think Ethicon had the only total kit in terms of a total Prolift, but I used the anterior kit and the posterior kit by American Medical Systems, the Elevate kit specifically.
Q. When did you use the AMS anterior and posterior kits?
A. I didn't use them very often, probably less than 20, but that would have been in and around 2007, 2008, maybe later, 2009, but it wasn't -- I didn't do very many of those kits.
Q. That was after you had been using Prolift?
A. The same time. I never stopped using Prolift. There was one particular hospital that only had the AMS product, and so I did use it there.

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Q. Did you receive formalized training from AMS regarding their products for prolapse?
A. Again, the word "formalize" is difficult to characterize. But what I received from American Medical Systems were PowerPoint presentations, videos, brochures, IFUs, things of that matter.
MR. KOOPMANN: Can we go off the record one second?
(Discussion held off the record.)
Q. (By Mr. Bentley) Doctor, we were discussing training, and you mentioned that some training that's available on products could be professional education activities; is that correct?
A. Correct.
Q. And sometimes those prof ed or professional education activities provide a certificate of completion at the end; is that correct?
A. Yes.
Q. Have you ever received a certificate for training related to Prolift?
A. Yes.
Q. Approximately when was that?
A. In 2004.
Q. And was that certificate given to you by

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Ethicon?
A. Yes.
Q. So Ethicon certified that you received the training on its Prolift; is that correct?
A. They gave me a certificate, yes.
Q. Did your hospital require you to present the certificate to be allowed to use the Prolift kit?
A. No, they did not.
Q. So what purpose -- strike that.
What utility did you get from the prof ed certificate regarding Prolift, if any?
A. I didn't feel the need to have the certificate. They just provided it to people who attended the course and actively participated and completed the course, so I went and watched another surgeon do a number of Prolift cases and then had reviewed the prof ed material that was provided to me, and we received some lectures, and then also attended a cadaver course.
Q. Is it fair to say that the certificate just certifies your attendance at the prof ed activity?
A. No, that's not fair.
Q. Was there some sort of a test or

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evaluation at the end of the prof ed activity that you had to complete to receive a certification?
A. There was no test.
Q. What was the -- strike that.
What did you have to do to receive the certificate from Ethicon for the Prolift prof ed training activity?
A. It would depend on who the individual was and what their level of training was. There was essentially three pathways to training. One pathway was from someone who was very experienced with prolapse kits and maybe were transitioning from one type of kit to another. Then there was the intermediate person who was very experienced in procedures that were similar in terms of graft-augmented repairs and trocar-based repairs. And then there was the surgeon who was doing primarily native tissue repairs. And so each one of those individuals needed a different level of training.
Q. And who would determine what level of training was appropriate for that doctor based on those three categories you just presented?
A. I think it was primarily up to the individual in terms of what they were requesting

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and what they felt their needs were.
Q. And then based off of that individual's personal assessment, they would attend whatever training they felt was appropriate; is that correct?
A. There was a dialogue between the trainee and the professional education manager and physicians that attended the courses, and so there's constant feedback that was provided in both directions. You would ask the individual what procedures have they done currently, what have they done in the past, what things they're comfortable what, what things would they like to learn more about.
Q. And the professional education manager, that would be someone working on behalf of Ethicon to teach about the Prolift product?
A. That's correct.
Q. And you actually taught on Prolift; is that correct?
A. I did.
Q. And in your experience teaching as a preceptor for the Prolift product, did you encounter that difference doctors had different experience in using transvaginal mesh placement for

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treating prolapse?
A. Yeah, I encountered all three levels that I described there of physicians.
Q. And did you have some test inside your head that you had -- strike that.
Did you have some requirement in your head that you had to think about before you would give this person a certificate of completing the training program, or was it simply they completed the training program that they felt was appropriate and you certified that they attended that?
A. I was one of the teachers, but I was not anybody that provided grades or a certificate or recommendations on who got the certificate. That wasn't something that I was part of the decision-making on.
Q. Did you -- strike that.
Was there someone present from Ethicon who would record who was in attendance at the training activity?
A. Record who was there?
Q. Yes.
A. Yes.
Q. Other than the preceptor?
A. Absolutely, yes. The professional

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education manager, the person who arranged the event, so each one of these events had to be scheduled and arranged and attended by an Ethicon personnel. They were never done in isolation in absence of Ethicon personnel.
Q. I think I've seen some brochures for the training program.
So typically how long would a Prolift training program have been?
A. I've seen some last as long as a few days, others a few cases. It would just depend on whether -- or what level that person was at. And then there was a lot of self-study that was required before they attended the course before they would be allowed to attend the course. So I can't say the exact hours. I can tell you what my own experience was and how many hours I spent training on Prolift.
Q. I'd appreciate that.
You're presenting opinions in your report about the adequacy of the training that was provided; is that correct?
A. Yes.
Q. And you're basing that upon your own personal experience; is that correct?

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A. Both as a trainee and a trainer.
Q. So if, for example, there was a training session for Prolift that was scheduled for, say, eight hours, would you expect that that full eight hours would be actually completed by the person in attendance to receive the certificate?
A. They had to complete the course, yeah. And I don't know who provided the certificate, but my general observation was people who attended the course attended all of the course, from start to finish.
Q. So you've testified and disclosed in your report that another basis for your opinions is your personal experience treating patients; is that correct?
A. Yes.
Q. Approximately how much of your time is spent treating patients?
A. I spend about 85 percent of my time in my clinical practice, which would include doing surgery and seeing patients in the clinic. While I'm seeing patients in the clinic and doing surgery, I usually have a student or resident fellow with me, so I'm providing education, so a lot of my education overlaps with my clinical

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practice.
Q. And can you approximate how much of your time is spent in surgery versus in clinic?
A. It's about 50/50. In a 20-day rotation, I spend 11 days in surgery and nine days in the clinic.
Q. And then of your time performing surgery, approximately how much of that is treating prolapse?
A. I don't have an exact number, but about 50 percent of the time I'm treating men and 50 percent of the time I'm treating women. And so of the 50 percent of the time I'm treating women, that would deal with incontinence and prolapse and other female pelvic floor disorders.
Q. Do you have an estimate how much of your time treating women is spent between incontinence versus prolapse?
A. There would be a greater percentage with incontinence.
Q. And then you also see patients for complications related to mesh; is that correct?
A. I see patients with complications from urogynecologic surgery.
Q. Other doctors refer more complicated

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cases to you for mesh complications sometimes; is that fair?
A. All sorts of complications.
Q. Do you feel that you're referred simple complications also?
A. Yes.
Q. Do you have an estimate of the time spent treating women of how much of your time is spent treating complications related to mesh?
A. In terms of number of cases I do per year?
Q. Sure.
A. I do somewhere around 35 to as much as 45 cases per year.
Q. Treating complications related to a mesh product?
A. Yes.
Q. Approximately how many surgeries do you perform a year?
A. About 500.
Q. Has that been pretty consistent throughout your career?
A. It's increased. As I've gotten older in practice, you become more efficient with your time, and there's a greater request of demand on your

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time, so at least for the last ten years it's between 400 and 500 cases per year. And that would include, you know, major procedures. I'm not including minor procedures that I perform in the office.
Q. Would the minor procedures include simple excision of mesh erosion?
A. It would not.
Q. You would consider that a more complicated case, using your characterization?
A. I would separate what I do in the office versus what I do in the operating room, so the minor procedures I do in the office would include transurethral bulking agents, cystoscopies, urodynamics, suprapubic catheter placement, urethral dilations. Those are the procedures that are in that category for office procedures.
Q. Do you perform any mesh-trimming procedures in the office?
A. Very rarely. I have in the past, and I might trim a suture, but not mesh. I did that for a very brief time and reported on that, and I didn't find that to be effective, so I stopped doing that.
Q. When you say it was ineffective, would

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there be a recurrence of the erosion?
A. Yeah, the recurrence rate was more than 50 percent. It didn't mean that all those patients were symptomatic, but it wasn't effective, so we went to an excision in the operating room. Patients were more comfortable, certainly, when we did that.
Q. Do you have an estimate of how many surgeries you do per year to treat prolapse?
A. To treat prolapse, probably somewhere -- anywhere between 50 and 100. It would depend on the particular year.
Q. And you've used a number of different procedures to treat prolapse based on the specific patient; is that correct?
A. That's correct.
Q. When you were using Prolift, do you have an idea of how many Prolift procedures you were doing per year?
A. I have a total. I don't have a breakdown based on year, but if you include Prolift and Prolift+M together, I've done close to 200.
Q. Do you have a breakdown between Prolift and Prolift+M for total numbers?
A. It's about equal.

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Q. So you think you've done about a hundred Prolift and about a hundred +Ms?
A. Correct.
Q. We've previously -- or strike that.
I believe you've previously testified that in incontinence products, there was an evolution of your practice and which products you preferred to use; is that fair? As we talked about earlier today, you may have evolved your practice to use Abbrevo more frequently than an obturator, the TVT-O full sling; is that correct?
A. That's correct.
Q. Did you have a similar evolution in your preferred product to treat between using Prolift versus Prolift+M?
A. Yes.
Q. And what was that preference?
A. Well, when Prolift+M became available, as I mentioned earlier in the other deposition, I tend to be a new adopter, or early adapter of procedures. And so similar for the +M. I was very interested in the technology and the biomaterials of the +M. And the rest of the system looked the same in terms of the trocars and the sheets, the retrieval devices. And so it seemed very logical

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to me, intuitive, that it would be a kit that I would want to try.
Q. And approximately when did you begin trying the new product in Prolift+M?
A. Let me look at my report, but I believe it was around 2007.
(Reviewed document.) So in 2006, excuse me, in 2006, I started using the +M system.
Q. In 2006, you believe you began using the +M system; is that correct?
A. I'm sorry. 2006 to 2012 is when I used those products. I'd probably say around -- probably around 2009 or 2010. Whenever +M became available, I immediately started using it.
Q. And once you started using it -- strike that.
Once you started using Prolift+M and you became comfortable with it, did that become your preferred prolapse mesh kit?
A. It did. I used that almost exclusively. There were some exceptions at certain hospitals. There was a transition between the two products, but eventually it became the only prolapse kit that I used.
Q. Doctor, I believe you've testified

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previously that you keep a case log of all of your surgical procedures; is that correct?
A. I do.
Q. And that would include surgeries where you implant the Prolift product; is that correct?
A. Yes.
Q. Did you review the case log specifically to see how many Prolift procedures you had performed before you prepared your report?
A. I did.
Q. So you got an exact number of how many Prolift products you had implanted?
A. I had an approximate number. I mean, the case log is nearly complete. I prepare that, for the most part, prospectively, but sometimes cases get cancelled or rescheduled and they may or may not appear on my case log. So I would say it's mostly accurate.
Q. Is it fair to say that your case log is one of the bases for your opinions in this case?
A. No, it's just a list of the number of cases, but I don't need to know how many cases I've done to prepare my opinions.
Q. That's right. Your case log doesn't track complications for Prolift implants; is that

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correct?
A. My case log doesn't, but I have, you know, reported -- I have one small study I did on Prolift where I looked at a small cohort of patients that I had treated with Prolift, and that involved a surgical video, and that study kept track of the complications.
Q. When was that study?
A. I don't remember the exact date, but I think it was around 2009, maybe 2008 or 2009.
Q. Is it cited in your report?
A. I would have to check. I don't see it here in my bibliography.
Q. Do you remember what journal it was published in, if any?
A. It was an abstract, so it was in the Journal of Urology. It was presented at the American Urologic Association meeting. The first author would be Pshak, starting with the letter P-s-h-a-k, Thomas Pshak. He was one of the residents who worked with me on the project.
Q. And what was the purpose of that study?
A. The study was to provide a video to inform and educate urologists on the Prolift procedure, also to perform a short review of our

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short-term results with the product.
Q. And when you say one of the goals was to perform a short-term review of your -- strike that.
When you say that one of the goals was to review your short-term results with the product, what was your end point that you were looking at?
A. The end point? It was a continuous list of all the cases that we had performed to date, so it included our first case, and then the most recent case that we did before preparing the abstract, so it was as comprehensive as we could make it. We looked at the outcome in terms of the efficacy and the prolapse resolution rate, and then we looked at the side effects or complications, such as stress urinary incontinence, mesh exposure, mesh perforation into the lower urinary tract.
Q. Do you know if that study is included in these binders that you brought today?
A. It's on the USB. I know for sure it's on the USB, both the video as well as the abstract.
Q. And do you know what the long-term follow-up was?
A. No, we don't have long-term follow-up.
Q. What was the follow-up in the study that you presented?

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A. It was minimal. It was less than a year.
Q. All right. So other than that abstract that you presented, did you do any other formal or systematic review of your case log regarding the Prolift patients that you had operated on?
A. There was a second abstract that compared healing abnormalities in two groups of patients, patients that had a single-layer closure, meaning we closed the vaginal wall just with one continuous suture, versus patients that had a -- what we call a double-layer closure, so we closed two separate layers of the vaginal wall, the deep fibromuscular tissue and then the vaginal epithelium.
Q. Why was that study performed?
A. I felt that a lot of the healing abnormalities were due to inadequacies in wound closure leading to wound dehiscence. So wound dehiscence will lead to mesh exposure. And so my thought was that if we can replicate what we do in other surgeries with the multi-layer-closure technique, we can decrease the incidence of mesh exposure.
Q. And did the study show that?

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A. The numbers were very small, so it was hard to show significant statistical significance, but at least the trend was that, yes, the double-layer closure seemed to be superior, at least in my hands.
Q. Would you agree that the erosion rate for the double-layer closure was zero percent while the single-layer closure was approximately 15 percent in your study?
A. I'd have to look at the study again, but that sounds about right in terms of the short-term results.
Q. And what was the length of follow-up in that study?
A. Again, it was fairly short, probably less than a year.
Q. With the Prolift procedure that's discussed in the IFU, does that recommend a single-layer closure or a double-layer closure?
A. I don't believe the IFU makes recommendations on how to close the surgical wound. That's up to the discretion of the physician. Most physicians, including myself, would close the wound, you know, the way they were taught to.
Q. But in your study, you demonstrated that

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the double-layer closure was much more -- was much safer because it had a lower erosion rate; is that correct?
MR. KOOPMANN: Object to form.
A. What I mentioned, that there was a trend towards better results in that group, but it was a small group with a short-term follow-up, so . . .
Q. (By Mr. Bentley) Do you know if some doctors are trained to use a single-layer closure?
A. That's how most people are trained. The single-layer closure can involve an interrupted technique, a running technique, a running locking technique. It can involve an absorbable suture versus a delayed absorbable suture. Some people will trim the vaginal wall, others won't. There's quite a bit of variability in wound closure techniques.
Q. And based on your experience that, you know, there's variability in how people are closing the wound, you did a study to determine whether there was a difference in safety based off of a single-layer closure versus double-layer closure; is that correct?
A. The only end point in the study was the exposure rate. We didn't look at other factors in

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terms of safety, but it was just looking at exposure.

Q. Would you consider exposure a safety issue?

A. I would consider it a complication. And most people would consider complications, you know, not safe.

Q. And exposure obviously can affect the patient's quality of life; isn't that correct?

A. Yeah, that's correct.

Q. And your study demonstrated that the exposure rate or quality of life was affected based upon using the double-layer closure; is that correct?

A. That's not correct. We never had any quality-of-life data in the study or qualified questionnaires in the study.

Q. So you think that . . .

Do you think that Ethicon should have shared with doctors your study results?

A. No.

Q. Do you think that patients would like to have a decreased erosion rate based off of a double-layer closure instead of a single-layer closure?

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A. I can't say what it's based on, but patients would prefer to have less complications, yes. That's obvious. Getting into how we close the wound, that's not something I ever really discuss with patients.

Q. Doctor, when you want to go back and look at your patients to see how, you know, your Prolift patients have -- how they have healed up to see who had erosions or complications or who's doing good, how do you perform that analysis on your patients, or on your patient data?

A. So most patients I tend to see at two weeks postop, at six weeks postop, three months postop, and a year. During each one of those visits I perform a history and physical exam, and I ask them very pointed questions on how they're doing. Are they satisfied? Are they having any issues with incontinence or prolapse? Are they having issues with infection? Are they having issues with pain or sexual dysfunction? I ask them if they're satisfied, if they're glad they did the procedure and had the procedure done. Are there other things that they're concerned about? And those are the questions.

The physical exam would include a full, you know, exam from head to toes primarily focusing on the abdomen and pelvis and the areas that the surgery was performed in. I check the prior surgical incisions. I check the entire vaginal wall. I look at the cervix, if that's present. I look at the urethra. I test their urine. I measure their postvoid residual. And then based on that initial assessment, I determine if other tests are necessary to evaluate.

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After a year, I ask them if they have other providers that they're seeing, if they have someone who's performing their annual gynecologic exam, to ask that person if they're comfortable continuing to follow the patient and include that in their exam. And if they do have someone local, then I would see if they're comfortable following up with that patient. If not, then they'll continue to follow with me.

Q. That's a fairly extensive list of data points.

Do you track those data points in any type of systematic way, or database?

A. No, they get entered into the electronic record. If we elect to perform a study, a retrospective study looking at a particular problem, then the data will be then organized, so the data is being put into the electronic record but not always collected or retrieved or organized or summarized.

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Q. And is that how you performed -- or is that how you collected the data for your two abstracts that we just discussed? You went back and looked at their electronic record; is that correct?

A. That's correct.

Q. Okay. And other than those two abstracts, have you gone back and reviewed the -- some of the electronic data available regarding your Prolift patients other than those two abstracts?

A. Since the FDA Public Health Notification, the FDA has asked physicians to keep track of that. So if someone comes in with a complication, then I would keep track of that, yes. But I'm not calling people, you know, after a year or sending out a mailing or anything like that. So if they're coming into my office with a complaint, or if another provider's seeing my patient and there's a complaint, then I would have awareness of that.

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Q. Okay. And I may have not asked a good question.

Other than those two abstracts that you've just discussed, have you gone back and reviewed the data that you have in the electronic records for your patients where you've implanted a Prolift? Have you done any type of systematic review of that data since those two abstracts?

A. I have not.

Q. Does your case log track patients that are referred to you from other doctors to treat mesh-related complications?

A. I don't know if "track" would be the right word, but, you know, when we visit with them, we do the best we can to obtain the prior operative report, and we will make a notation of what product they had put in previously, whether they're doing well or not well. So it's part of our general intake.

When someone comes in with any disease process, we ask them if they've had prior surgeries. What are those surgeries. We try to get as much detail as we can, including the operative reports on those surgeries, especially if we're going to plan on doing another surgery in a

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similar area.

Q. I think we've previously discussed, your case log doesn't necessarily track all of that information; is that correct?

A. The case log doesn't. Again, it would come back to doing a specific study. The study I didn't mention was one that was presented last spring at the American Urologic Association where we looked at 82 complications from prolapse kits that we had managed.

Q. Okay.

A. And Dr. Kirk Anderson, who was my fellow at the time, he had presented that data, those 82 patients that we managed. The overwhelming majority of the patients had been referred to me. Some of the patients were my own patients.

MR. BENTLEY: Are we at a good point for lunch? Is that right? I think we're about an hour in. Is that right?

MR. KOOPMANN: Let's go off the record for a second.

(Recess taken from 12:58 p.m. until 1:08 p.m.)

Q. (By Mr. Bentley) Doctor, we're back from a quick break. Are you ready to go?

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A. Yes.

Q. Before the break, we were talking about your case log, and I just wanted to wrap up -- I was asking -- I believe you testified that you didn't do any type of systematic review of your case log to prepare for your Prolift report; is that true?

A. That's correct.

Q. And likewise, you didn't do any type of systematic review of your case log for your Prolift+M patients to prepare for that report either; is that true?

A. Correct.

Q. And so in reaching your opinions in this case, you're not relying upon any type of systematic review of your own case log to reach your opinions here; is that fair?

A. That's fair.

Q. And similarly, you're not relying on any type of systematic review of the patients you've treated for erosion or other complications in reaching your opinion here; is that fair?

A. I did mention the one study before the break recently that we looked at 82 complications that we had managed related to prolapse kits, so

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that certainly affects my opinion and my thoughts on this process.

Q. Sure. Other than that, you haven't done any type of systematic review of the complications you've treated, such as erosion, in preparation for your report or in preparation for this deposition; is that fair?

A. Well, in that review, there's the whole review, the whole -- it's not a review, it's an abstract. But in the abstract, it focuses on what we did to manage those patients and what techniques worked and what didn't work.

Q. And that abstract's not going to present some type of erosion rate such that you're going to be able to testify based off that abstract what percentage of the patients you treated had an erosion; is that fair?

A. What patients I implanted?

Q. Sure.

A. Yeah, correct. It won't -- it doesn't reflect my own personal exposure rate on patients I implanted.

Q. And you can't calculate from that abstract an erosion rate for other doctors; is that fair?

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A. Correct.
Q. Doctor, we have briefly discussed a little bit, and I believe you mentioned that another bases for your opinions in this report is the body of medical literature out there; is that true?
A. Yes, that's true.
Q. And I think you mentioned that you've performed PubMed searches to identify articles regarding prolapse and Prolift; is that true?
A. That's true.
Q. And did you perform a PubMed search in preparation for reaching your opinions in this case?
A. I did.
Q. And do you know what the keyword searches you used to perform that search?
A. I used the word "Prolift."
Q. Okay.
A. "Mesh," "mesh kit." I believe that was it. Probably just those two words.
Q. Do you have an idea of how many articles that search would have returned?
A. With respect to the prolapse search, I would think somewhere around 30 or 40 articles.

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Oftentimes the word "Prolift" doesn't appear in the title even though the article is specifically about that product.
Q. I think I misunderstood.
Is it your testimony that you performed two different PubMed searches, one using the keyword "Prolift" and maybe a second keyword search using the key words "mesh kit"? Is that accurate?
A. I'm not certain if that's accurate, but I know I recalled doing a PubMed search. The exact key words I used, I know I would have at least used those two words. I may have used other words, or similar words.
Q. It's fair to say that you didn't have any type of systematic approach to how you were performing your PubMed search; is that true?
A. Usually when you put in a search word, you'll get some articles, and then they'll show articles in the column on the right of that that are similar to those articles, and it kind of just leads you to deeper searches. So you put in that search word, and you end up looking at a lot of different articles maybe that aren't immediately from that first search word, but it's sort of a chain reaction once you start looking at PubMed.

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Q. Okay. I appreciate that, but my question was a little different, Doctor.
Is it fair to say that you didn't have some type of systematic approach to how you searched PubMed for articles in preparing your report?
A. Correct.
Q. Okay. And likewise, did you perform any type of systematic search on PubMed to find articles related to Prolift+M in preparing that report?
A. I did the same type of search for Prolift and Prolift+M.
Q. And subsequent to issuing your reports, have you done any type of systematic search on PubMed in preparation for the deposition today on Prolift or Prolift+M?
A. Since issuing these reports?
Q. Yes.
A. No, I have not.
Q. I would assume it's your general practice to read very scientific articles that are published that concern your practice; is that fair?
A. Yeah, there's a number of journals that I read commonly. We have a journal club that's part of our practice. We do that at least a few

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times a year at the University of Colorado with our residents and students, and so I am a reviewer for a number of journals, so sometimes articles will be sent to me as a reviewer, so I am looking at the medical literature very commonly.
Q. Do those journal club activities discuss, say, mesh-related articles?
A. They do. We just discussed one recently a few weeks ago.
Q. When, approximately, was the last journal club that you attended?
A. That would have been two weeks from tomorrow.
Q. And I believe you just testified that you do -- or you attend journal clubs approximately quarterly; is that fair?
A. I would say there's at least five or six a year that I attend.
Q. Okay. So subsequent to issuing your report on February 26, how many journal clubs have you attended?
A. Since February?
Q. Yes.
A. One or two.
Q. Okay. And did those journal clubs

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identify any important new mesh-related articles that you felt changed or affected your opinions in this case?

A. Well, one article that had come up in my last deposition was the Welk article from Canada. It was a JAMA article, so that was one that -- JAMA is a very large journal that has high readership, and so we felt that that was important to review.

Q. Would you expect that attending these journal clubs would keep you apprised of the important literature that's being put out there regarding your practice and, specifically, Prolift and mesh kits?

A. It's one of many ways. It's part of the process, that as well as attending scientific meetings and discussion with colleagues, my own personal review of the literature in the journals that I subscribe to.

Q. When you're reviewing these scientific articles regarding Prolift and mesh kits for treating prolapse, is it fair to say that there's strengths and weaknesses with any given article?

A. Yes.

Q. Can you describe for me what strengths you would look for in an article to use to reach

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your opinions in this case?

A. Well, we usually start out by looking at the pure size of the article, how many patients were enrolled. Then we look at the methods. Was this prospective or retrospective? Were patients randomized? Was there more than one center involved, maybe more than one surgeon involved? Those things factor into what we consider levels of evidence. Was it an actual study where patients were enrolled, or is it more of a review, systematic review or meta-analyses?

So we look at the number of patients, the format of the study. We look at what journal it was published in to see if the journal was peer reviewed. That's also important.

Sometimes I might know the authors. People that I know, I tend to follow. And, you know, I'm interested in reading what they have to write, my mentors, especially, and thought leaders that I respect in SUFU and AUGS. So it's a process. But briefly, that's the process that I adhere to.

Q. Do you feel that the articles that you cited in your report met those tests for whether an article is strength -- or has strength?

A. Well, the report has various levels of

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evidence and support. The reports that we were talking about earlier, my small case series of the double-layer closure and the Prolift video, those were low-level evidence. Some people call them pilot studies or case series. We do those studies as way of encouraging scientific research by our residents and fellows. It gives them an opportunity to present. But I don't rely on those as heavily as I do on systematic reviews and the meta-analyses.

Q. Would you agree that all of the articles that you have cited in your paper are all from authors that you respect?

A. No, I wouldn't agree with that.

Q. Are there certain authors that you've cited to that you don't respect in your paper?

A. I think that would be too strong of a word. I mentioned they're some of the authors I know, but I would say overwhelmingly I don't know the majority of these authors personally, so I can say there's a number of authors that I have a personal relationship with that I know, I've met, I've had personal communication with, but 90 percent of these authors I've never or I never will meet, so it's hard for me to say if I respect them

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or not.

Q. Aside from the strengths that you just described, are there any weaknesses that you look out for that might discount an article other than the lack of the strengths that we just discussed?

A. Okay. So if it wasn't in a peer-reviewed journal, I'm concerned that maybe they've attempted to publish it in a peer-reviewed journal and it was turned down, so they went to a second- or third-tier-level journal, so that's something that may be a red flag, although, occasionally, you'll find very good articles in journals that aren't peer reviewed. It's quite variable. Just the whole opposite of what I just said. If it's small numbers, if it's not multi-center, if it's not randomized, if there's not long-term follow-up, you know, those are going to be weaknesses.

Q. Right. So other than the lack of the strengths that we've discussed, there's no -- you can't identify right now any weaknesses that you look out for other than the strengths or the lack of strengths that we just discussed?

A. Well, getting back to the journals, if it's not a peer-reviewed journal, that's considered

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a weakness. If the follow-up is short, that's a weakness.

Q. Generally, what follow-up are you looking for when you're evaluating a study that's discussing Prolift and mesh kits to treat prolapse?

A. Well, I look primarily at how long the procedure's been performed over how many years. So if the procedure's only been available for a year, then I'm very interested in looking at the short-term follow-up, because that's all you're going to get. That's the best available information that's available to you. TVT product has been available for -- since 1998, so it doesn't make sense for me to look at a study that has less than, say, three- to five-year follow-up, so the longer the product's on the market, the more you're going to rely on long-term follow-up. For newer products, the best you can rely on is short-term follow-up or intermediate follow-up.

Q. Right. And my question was specific to Prolift and mesh kits to treat prolapse.

What follow-up are you looking for to evaluate whether a study has the strength that you need to rely upon it for your report?

A. I'd like to see a minimum of one year.

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And ideally, I'd like to see three years or more.

Q. When you're evaluating the strengths and weaknesses of various articles and ultimately reaching a decision of whether or not you're going to include it in your report, is it fair to say that you're not performing any type of epidemiological analysis on the numbers presented in the case? Is that fair?

A. I'm not performing the study. I'm only reviewing the study, so it's really up to the author on how they design the study. Then I look at that study, and I use that as the basis of my opinions in this report.

Q. Right. So you're not performing any type of follow-up, epidemiological or statistical analysis on the study. You're just taking the study as presented and deciding whether or not it meets your inclusion criteria for your report; is that fair?

A. Yeah, that's fair.

Q. And, in fact, you're not an expert in doing epidemiological analysis; is that fair?

A. I have some expertise in epidemiology. I spend a lot of time reviewing the medical literature, looking at meta-analyses and systematic

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reviews. I understand incidence and prevalence and epidemiologic factors.

Q. Sure.

A. So it's really not up to me to decide if I'm an expert, but I think I do provide expertise in those areas when discussing papers with my patients, with my residents, the fellows and students that I educate.

Q. You don't publish on epidemiological practices; is that fair?

A. Not on practices, but it includes -- it's in almost every article we write. That's always in the introduction. There's going to be a short blurb on epidemiology of the disease, the prevalence of the disease, who it affects, you know, so that people understand the magnitude of the problem.

Q. Of course. And you've never published in any journals like statistics or epidemiology, right?

A. On the mathematical methods?

Q. Right.

A. No, I have not.

Q. Of course.

Okay. Now, I think you testified that you

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rely upon the studies as presented; is that fair?

A. I would need more information on that one.

Q. Okay. For instance, if there was a problem with some of the measurements in obtaining the data for a study, you wouldn't know that because you're not getting the patient-level data for the study; is that fair?

A. I don't think I can respond to that. If you can repeat that again. I'm sorry.

Q. Sure. For example, if there was a problem with the reliability of the POPQ measurement in a study, would you want to know that before concluding whether or not that study was reliable upon which you could reach your opinions?

A. I have no reason to believe the POPQ wouldn't be reliable. It's something that's been well-standardized and utilized in many studies.

Q. I'm sorry.

If there was a problem with how the POPQ was collected in a specific study and it didn't say that in the publication, you wouldn't know that by your review, say, in your journal club of that study; is that true?

A. Some authors mention who did the POPQ,

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and others don't, so it's a stronger study, generally, if it's a third party, meaning the person who didn't do the surgery does the POPQ, for instance, like the surgeon's nurse or partner or physician assistant. And oftentimes surgeons will mention that. You'll see that more commonly in more recent reports.

Q. Let me back up.

Could you define POPQ for me?

A. POPQ is the pelvic organ prolapse quantitation score. It's something that had been described at least 15 years ago. I remember learning about it when I was a fellow at Duke University. I studied there under George Webster and Cindy Amundsen, Allison Widener and other great thought leaders, and so they taught me how to do the POPQ.

What it involves is using what we call a measuring stick. This looks like a popsicle. Sometimes there's markings on a metal stick. And that would be inserted into the vagina and used to take measurements, including the total vaginal length, the length of the genital hiatus, the perineal body. And then there's points on the anterior wall and the posterior wall, AA, AB, PA

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and PB. And so you end up putting the numbers in what looks like a tic tac toe board, you know, so you have some cross hairs with nine boxes, and then you put your measurements in there. The idea is that's a more scientific way of quantitating surgical outcomes compared to, say, mild, moderate, severe prolapse or stage one, two, three, four.

So the whole idea of POPQ was to be able to get individual measurements in all the different compartments. And it's something that's been popularized and standardized. When I prepared for my exam and my certificate and my board certification in female pelvic medicine and reconstructive surgery, I had to learn about POPQ and statistics and epidemiology and all these things. So I learned it as a fellow, and then I relearned it again when I was preparing for the exam, and I use it in my practice.

Q. Right. So essentially, it's a way of measuring the stage of prolapse, is that fair, to sum it up?

A. More than just stage. I think it gives you more detail beyond stage than, say, the Baden Walker. It tells you which compartments specifically are prolapsed.

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Q. Okay. And it can be used to gauge whether there was recurrence after a woman was treated for prolapse; is that true?

A. Yes, that's true.

Q. And going all the way back to my hypothetical, if there was a problem at the data-collection level when the doctors were determining the POPQ after they treated the woman for prolapse, if there was a problem in that data collection and you didn't know about that, you wouldn't have that information available to you when you read the study; is that fair? You can't tell patient-level data from most of the studies unless the authors put it in there; isn't that fair?

MR. KOOPMANN: Object to form.

A. I mean, the authors will put it in there, and generally, if it's from a peer-reviewed journal, we're going to believe it.

Q. (By Mr. Bentley) Do you know if, during the peer review process, if most journals review all of the patient-level data?

A. No, the reviewers -- as a reviewer, I can say, when I review papers, I don't see the actual spreadsheets. I see the manuscript. I see

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tables. I see graphs, figures. If something doesn't seem right to us, we'll send it to an in-house person for statistical review to make sure that the statistics make sense if they're using a complicated statistical model. And then we have an opportunity to send feedback to the authors and ask them to respond to our comments. And if those responses are not satisfactory, then we don't publish the article.

Q. Sure.

Doctor, in your career, have you ever been involved in writing or preparing warnings for a medical device?

A. Have I ever prepared a warning?

Q. Yes.

A. No. I've prepared a response to a warning, but I've never written a warning.

Q. Do you have an opinion as to what warnings are required to go into an IFU?

A. Yeah, I have some general requirements on what the FDA would like to see in an IFU and other types of literature.

Q. Okay. Let's break that down.

What are your general requirements for what you expect to be in an IFU regarding warnings?

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A. I want to hear if there's information on toxicity. I want to hear if there's information on carcinogenesis. I want to hear about complications that might be unique to that product that's not part of ordinary urogynecologic practice, so things that don't happen with everyday surgery that maybe is more specific or unique to that product. Those are the warnings that I'm interested in seeing.

Q. So is it your opinion that warnings don't need to be included in the IFU if doctors generally know about the risks already?

A. You have to separate what's fundamental surgical knowledge with urogynecologic surgery versus what's more product-specific and related to the product.

Q. Okay. And is that standard for warning based on Dr. Flynn's general requirements or are you basing that upon some other standard?

A. That's based on the standard that was taught to me as a resident fellow and the standard that I see used in my practice and the practice that I participate in with my partners and the students and residents that we train. So it's not my own personal standards. It's the standards that the professional societies that I belong to adhere

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to, as well as my partners and colleagues around the country.

Q. Is that standard based upon some FDA rule?

A. I think that the FDA gives us information and gives us guidelines. I've reviewed guidelines from the FDA about what they'd like to see.

MR. BENTLEY: I'm going to strike --

A. But they're not rules.

MR. BENTLEY: So I'm going to strike as nonresponsive. My question is a little different.

Q. (By Mr. Bentley) Is your standard that you just discussed based upon some FDA rule?

MR. KOOPMANN: Object to form.

A. I can speak to standards and guidelines. I don't know if that substitutes for rules.

Q. (By Mr. Bentley) We don't want you to guess.

A. Okay.

Q. Just -- you don't know of any FDA rule that you're assigned to right now that supports or that is -- strike that.

The general requirement that you just discussed, do you know if that's based on any

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specific FDA rule as you sit here today?

A. I do.

Q. And what rule is that specifically based on?

A. Well, I think if you look at the FDA Public Health Notifications, the two that were published, I believe 2008 and 2011, I could be off on the years, but the FDA specifically gave a notification to physicians on certain things, so those are things that I think are important for us to consider as surgeons in our discussions with patients when gaining informed consent.

Q. Doctor, I'm going to strike as nonresponsive.

My question is, what rule are you referring to with regard to your requirement as to what's required in an IFU regarding warnings, not a Public Health Notification?

A. Okay. I'm sorry if I missed the question. I'm also familiar with the FDA recommendations that were put out in the '90s in the blue book, and they gave some general guidelines, some would call them rules, on what should be included in, you know, medical literature or IFUs.

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Q. That's fine.

And so is it your testimony today you don't know any specific statute or law that mandates what warnings need to be included in an IFU? Is that fair?

A. That's fair.

Q. Is there any internal Ethicon standard that you're aware of that sets out what warnings need to be included in an IFU?

A. I'm not aware of any internal standards. I believe they would just adhere to the industry standards.

Q. So you don't know that Ethicon has its own internal standards that mandate what it has to warn about in labels?

A. No, I'm not aware of what their internal standards are.

Q. Would you have liked to have reviewed those internal standards in reaching your opinions today in this case regarding the adequacy of Ethicon's warnings regarding its own product?

MR. KOOPMANN: Object to form.

A. No.

Q. (By Mr. Bentley) You don't care what Ethicon's internal standards are regarding its

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warnings?
A. I do care. I think that they're a very reputable company, and I believe that they would adhere to whatever industry standards are.
Q. So you would expect that Ethicon followed its own standard in deciding what warnings needed to be included in its IFU for its product such as Prolift?
A. Yeah, the --
MR. KOOPMANN: Object to form.
A. -- internal and external standards.
Q. (By Mr. Bentley) But you don't know what those standards are because you haven't reviewed them?
MR. KOOPMANN: Object to form.
A. No. I don't know. Sorry.
Q. (By Mr. Bentley) And as you sit here today, other than toxicity and carcinogenesis, what other warnings would you want or expect to be in a Prolift IFU?
A. I think what I mentioned also was unique complications to Prolift that maybe don't occur with ordinary urogynecologic surgery.
Q. Right. And that's my question. What complications do you think -- based off of that

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definition or that explanation, what complications -- you as Dr. Flynn, using your general requirements that we discussed, what warnings, in addition to the toxicity and carcinogenesis, would you want or expect to be in the label for Prolift?
A. I would like some information on patients that were contraindicated to the procedure, so for instance, if the patient's pregnant, if the patient has bleeding diathesis, if the patient has chronic vaginal infection or -- you know, those are things that, you know, I certainly would want to be aware of. Other things I'd want to know about is the risk of mesh exposure or healing abnormalities, injury or damage to surrounding structures like the bladder or the urethra or the bowel, nerves, blood vessels. So I want to know what organs can be injured. I want to know what the exposure rate is. I would want to know, obviously, if there's any concerns about the product causing cancer or causing any untoward side effects to the patient.
Q. Doctor, I believe you testified that you'd want Ethicon to include warnings that were unique to the product and the label; is that fair?

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A. Yes.
Q. And you just told me that you would like to know that there's a risk of damage to the nerves, to blood vessels or bowel. Is that -- are those risks unique to the Prolift device?
A. They can be, or they can be part of ordinary surgery, but you'll see both possibilities.
Q. But you would like for those risks to be included in the label; is that true?
MR. KOOPMANN: Object to form.
A. I think that those risks that I mentioned are ones that I've seen in the IFUs for the various products, the Ethicon products that I'm familiar with.
Q. (By Mr. Bentley) But are those risks inherent with general surgery other than the Ethicon products?
A. Yes, they can occur with general surgery, native tissue repairs and other graft-augmented repairs, sacrocolpopexy. Certainly, any surrounding structures can be damaged when you're operating near or around them.
Q. Right. And you want those risks to be warned of in the Prolift label; is that correct?

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A. Yeah, that's correct.
Q. Using your method or your general requirements for determining what warnings should go into a label, how did you decide that those risks that are also inherent with general surgery were appropriately put in the IFU for Prolift, as you just testified?
A. I think that what's unique with, say, Prolift compared to a native tissue repair is the graft material and then the devices that are used to place the graft material, the inserters or tunnelers, you know, those devices.
Q. I'm sorry. I'm just not understanding, I guess.
How is it that these risks that you're discussing that are inherent with general surgery you expect them to be in the Prolift IFU, such as potential risk for injury to bowels, to nerves and to blood vessels? Why do you think that these general risks of surgery are appropriately put in the IFU for Prolift?
A. Because that's what I've seen in other IFUs that I've reviewed. It seems to me like that is may be a standard that exists for, say, the TVT product or other types of mesh kits.

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Q. So your method for deciding whether or not these risks should be included in the IFU is based on what you reviewed in other IFUs; is that true?
A. That's part of it, yes.
Q. And in addition to that, what else is your opinion based upon?
A. It's based upon my own personal experience and things that maybe you felt that you didn't have a way of knowing based on your current experience or education.
Q. Okay. And we've previously discussed that you're aware that different doctors have different experience levels with these mesh products; isn't that fair?
A. That's correct.
Q. And so maybe including some complications that you're aware of as more of a specialized expert in your field might be helpful for some other doctors that aren't as highly trained; would you agree with that?
A. Yes.
Q. Doctor, prior to writing your report, did you already hold the opinion that Prolift was safe and effective?

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A. Yes. I used it for a number of years in my practice, and so I wouldn't have used it for that many years if I didn't feel it was safe and effective.
Q. Is Prolift currently on the market?
A. Prolift is no longer on the market.
Q. Do you have an understanding of why Prolift is no longer on the market?
A. I have some understanding, but it was a decision that Ethicon made to voluntarily no longer offer the product.
Q. Did Ethicon receive a 522 order from the FDA regarding its Prolift product, if you know?
A. I don't know if they did or not, but I do know that they made that decision voluntarily to no longer offer the product.
Q. Do you know what a 522 order is?
A. I do.
Q. Could you tell me?
A. 522 -- five hundred and twenty-two, five-two-two -- is a code in the FDA regulatory system as opposed to, say, 510 or 510(k), so there's different ways the products go through regulatory. And the 522 was ordered on mini-slings and transvaginal prolapse kits. The 522 requires

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analysis of post-market or -- devices that are currently on the market, so these are devices that are already approved, and they ask the manufacturers to prospectively collect data on the devices and then to -- I think they have two years or so to report to the FDA on what they find.
Q. So is it your testimony that a 522 order requires the manufacturer of a device to perform additional post-market studies to determine the safety of its device?
A. Yes.
Q. And if Ethicon was ordered by the FDA to perform 522 studies, does that affect your opinion in this case?
A. No.
Q. Do you know if Ethicon chose to withdraw the Prolift product from the market instead of doing the 522 studies?
MR. KOOPMANN: Object to form.
A. I don't know what their motivation was.
Q. (By Mr. Bentley) Would you have liked for Ethicon to do additional safety studies?
MR. KOOPMANN: Object to form.
A. I would have liked to see Prolift or Prolift+M stay on the market.

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Q. (By Mr. Bentley) When the FDA issued its 522 order to Ethicon regarding its Prolift product, do you know if Ethicon submitted studies that already existed to the FDA in an attempt to get out of having to do additional studies?
MR. KOOPMANN: Object to form.
A. I'm not aware of what sort of internal strategies they had for dealing with the 522s.
Q. (By Mr. Bentley) Do you know if Ethicon submitted the very studies you're relying upon -- in this report to reach your opinions, do you know if Ethicon submitted those very studies to the FDA to get out of the 522 study requirement?
A. I don't know.
MR. KOOPMANN: Object to form.
Q. (By Mr. Bentley) Assuming that happened, if the FDA then reviewed those studies and still determined that Ethicon needed to do additional studies pursuant to a 522 order, would that have affected your opinion in this case?
A. No.
Q. So you don't think it's of any importance that the FDA might have reviewed the same studies that you reviewed and determined that the safety and effectiveness of the Prolift has not

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been established?
MR. KOOPMANN: Object to form.
A. That misstates what I said. I think that the FDA has, you know, some goals and some things that they need to attend to -- but how I prepare my report, was that the question? And the way I prepared my report was, aside from the 522 orders, whether the 522s were ordered or not ordered, I would have prepared the report the same way. It didn't affect how I thought about the product.
Q. (By Mr. Bentley) Do you have any understanding of whether or not the FDA employs a number of epidemiology experts to review safety data for products that it's monitoring?
A. I don't know who the FDA has on their staff. No, I don't.
Q. Would you expect the FDA to have very highly trained and skilled professionals to review safety data?
A. Yes. I know a lot of them are physicians.
Q. And we've already discussed that you didn't perform an entire full systematic review of the literature; isn't that fair?

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MR. KOOPMANN: Object to form.
A. I don't think that's fair, no.
Q. (By Mr. Bentley) What level of evidence would you consider your report in the sections that review the literature on Prolift? Would you -- could you characterize what level of evidence using the Oxford Levels of Evidence for me?
A. The report has all four levels of evidence. When I get into the sections on the systematic reviews, such as the Cochrane review, you know, and the RCTs, those would be highest levels of evidence. When I talk about my own personal experience with the device, my background and maybe some of the pilot studies, that would be the lowest levels of evidence. So it's a long report with various levels of evidence.
Q. But the section specifically reviewing the medical literature available for Prolift, you wouldn't consider your section reviewing that literature to be a systematic review, right?
A. That's correct.
Q. Would you think that the FDA would be better enabled to do a systematic review of the medical literature than you?
MR. KOOPMANN: Object to form.

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A. This is not a systematic review. It's a report. I think I've testified to that.
Q. (By Mr. Bentley) My question: Do you think the FDA is equipped and qualified to do a thorough systematic review of the medical literature regarding Prolift?
A. Of course, yes.
Q. And so in doing that analysis, if the FDA determined that the studies you relied upon in this report are not sufficient to establish the safety and effectiveness of Prolift, you don't give that conclusion by the FDA any importance in your report?
MR. KOOPMANN: Object to form; foundation.
A. I wouldn't use the words "any importance." It's just one of many pieces of information that I use to formulate my opinion.
Q. (By Mr. Bentley) If that had happened, would that be important for you to review at least?
A. I can't answer that. I mean, we're speaking in the hypothetical. I don't believe it's happened, so I can't answer that one way or another.
Q. Because you haven't been provided any documents demonstrating what Ethicon provided to

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the FDA; is that fair?
A. That's fair.
Q. And if, in fact, that had happened and you had been provided with those documents showing that Ethicon provided to the FDA the same studies you relied upon, and the FDA concluded it's not enough to establish safety and effectiveness of Prolift, and they still ordered Ethicon to do 522 studies -- if you had been given all that information, would that maybe have affected your opinion in this report?
MR. KOOPMANN: Object to form.
A. No, I don't think so.
MR. BENTLEY: Could we take lunch?
MR. KOOPMANN: Sure.
(Recess taken from 1:48 p.m. until 2:48 p.m.)
Q. (By Mr. Bentley) Doctor, we're back from a short lunch break. Are you ready to go?
A. Yes.
Q. When you're discussing with your patients whether to use the Prolift implant to treat prolapse, would you perform a risk-benefit analysis with the patient?
A. I wouldn't call it analysis, but a

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risk-benefit discussion.
Q. And you would discuss the potential complications with the procedure with the patient?
A. I would.
Q. And in your report, it's your opinion that Prolift has a favorable risk-benefit analysis; is that correct?
A. That's correct.
Q. And in reaching that opinion, you evaluated all the potential risks associated with Prolift; is that correct?
A. Correct.
Q. And you balance those against the potential benefits; is that correct?
A. Yes.
Q. And when you're talking about benefits of the Prolift, is one of the aspects of that analysis how Prolift compares in success rates regarding occurrence as compared to other procedures to treat prolapse?
A. Yes.
Q. And one of the other major alternative procedures to treating prolapse is native tissue repair; is that correct?
A. Yes.

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Q. And it's your opinion that Prolift is significantly more efficacious than a native tissue repair; is that correct?
A. Yes.
Q. And in your report, actually on page 8, you cite to the 2013 Cochrane review by Maher for that very proposition; is that correct?
A. Yes.
Q. And I think we've previously discussed you believe that the Cochrane review to be a high level of evidence, according to the Oxford Levels of Evidence; is that correct?
A. Yes, that's correct.
Q. When you discuss with your patients the risk-benefit analysis of Prolift, do you also tell them that you believe that Prolift is more efficacious than native tissue repair?
A. I do.
Q. And when you're discussing the risks associated with Prolift, do you discuss with your patients the potential for Prolift to induce a foreign-body reaction?
A. I don't use those words specifically. I talk to them about having postoperative pain or exposure.

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Q. Okay. Do you have an understanding of whether or not Prolift and the polypropylene mesh that Prolift is made of induces a foreign-body reaction in the body when implanted?
A. I have opinions on that, yes.
Q. Okay. Do you agree that there is a foreign-body reaction associated with the implantation of Prolift in polypropylene meshes to treat prolapse?
A. Yes. Any foreign body is going to cause a foreign-body reaction.
Q. Sure. And some foreign bodies might have a higher degree of foreign-body reaction as compared to other foreign bodies; is that fair?
A. Yes.
Q. And with a foreign-body reaction, does the body sometimes create a scar plate as a consequence of that process?
A. Yes.
Q. And, in fact, in your practice, have you seen patients have complications from mesh-related implants where the patient has, in fact, suffered from a rigid or hardened scar plate? Is that fair?
A. Yes.
Q. And sometimes you have to remove that

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hardened scar plate where the body has become encapsulated in the mesh and it's become a hard scar in the body; is that correct?
A. That's correct.
Q. And that scar plate process can, in fact, lead to other complications, such as pain; is that correct?
A. I mean, it can lead to a variety of complications, including pain.
Q. And absent that mesh implant, there's not going to be a foreign-body reaction to a mesh. Makes sense, right?
A. If there's no foreign body, then there wouldn't be a foreign-body reaction, but there is some reaction to surgery, and especially if there's permanent sutures being used.
Q. Right. And, of course, the surface area of the polypropylene mesh, or the total polypropylene material used in a Prolift implant is substantially greater than that used -- or that in a suture; is that correct?
A. Yes, that's correct.
Q. Do you have any understanding of the relative size comparison to a Prolene suture versus how much polypropylene mesh is placed in the body

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with a Prolift mesh implant?
A. I never have seen a comparison. I mean, with the suture-based repair with permanent stitches, it'd probably be anywhere from three to six sutures being used. You know, the Prolift implant is obviously much bigger than that.
Q. Approximately how long would one of those sutures be where you say that you use approximately three to five sutures?
A. Well, they're very long, but then you tie them together and you cut the knot. So how long is the knot? Less than a centimeter.
Q. Okay. And do you have any understanding or appreciation of how much length of polypropylene goes into making the Prolift mesh that's permanently implanted in the woman's body?
A. I do.
Q. How much is that?
A. I believe, going from right to left, it's somewhere around 8 to 10 centimeters.
Q. And that's for the entire implant, correct?
A. For the anterior implant.
Q. Okay. And my question was a little different.

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The Prolift implant is actually knitted together using polypropylene-extruded resin; is that correct?
A. It uses fibers of the polypropylene, and, yes, it is knitted together.
Q. Okay. And my question is, do you know or have an understanding of how much fiber, how much polypropylene fiber goes in -- that is knitted together to make the Prolift mesh material?
A. In terms of weight?
Q. No, total length.
A. Total length? Well, I mentioned you have 8 centimeters right to left, and I believe it's somewhere around 10 to 15 centimeters anterior to posterior.
Q. I apologize. It's probably a bad question.
But how much do you -- if you know, do you have an understanding of what length of polypropylene fiber it takes to knit together to make the approximately 8-centimeter Prolift implant?
A. I don't know the number.
Q. Do you have any estimate or idea of whether it's substantially more than a couple

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centimeters of Prolift -- I'm sorry, of Prolene suture?
A. Yes, it's certainly -- you know, it's 8 centimeters wide, so it's easily at least 8 centimeters.
Q. And that 8 centimeters is comprised of however much Prolene fiber it took to knit together to make that implant, right?
A. Yes.
Q. Okay. And assuming that there's a foreign-body reaction to the polypropylene suture, would you also expect that there's a foreign-body reaction to the polypropylene that's used in the Prolift mesh implant?
A. It's the same material, so you'd have a similar reaction.
Q. Except for you have a much larger quantity of the material in the human body when you implant the Prolift mesh implant as opposed to a couple of sutures, correct?
A. Correct.
Q. And related to that, you would expect that the foreign-body reaction would be greater because there's more material for the body to be reacting to. Would you agree with that?

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A. I would agree to that.
Q. Okay. In your experience, have you ever had to remove a hardened scar plate that has happened as a consequence to the body having a chronic and persistent foreign-body reaction to a suture?
A. Well, I can't say how it happened, but I removed scar plates.
Q. And would the scar plate that's associated with a suture-foreign-body-reaction process be substantially smaller than the removed tissue and mesh from a Prolift implant?
A. Yes.
Q. So the Prolift revision surgery to take out the mesh, including a section of the tissue that's ingrown into it, would be much more invasive and much more serious than removing the counterpart for a suture; is that correct?
A. Yes, that's correct.
Q. Do you discuss that increased risk with your patients?
A. I discuss all the complications. I discuss the need for revision surgery and removal. I don't think I go into that much detail on how a revision would be done. I tend to focus more on

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how the original or initial surgery would be done.
Q. Do you think a patient would be interested to know what the level of severity is associated with treating a complication with the Prolift procedure as compared to what level of revision surgery might be associated with, say, a native tissue repair using suture?
A. I think that's probably more information than most patients desire.
Q. You don't think a patient's concerned about the level of severity of a revision surgery?
A. No.
Q. Does the level of revision -- strike that.
Does the severity of a revision surgery lead to further complications?
A. Well, any time a surgery is going to take longer or be more invasive, there's going to be increased risks.
Q. Approximately what's the size of removal when you have to take out a substantial portion of the Prolift that's been integrated into the body? Approximately, in your experience, what's the size of the mesh and tissue piece that you take out?
A. Every case is different, but generally

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we will take out the part that extruded or exposed. I use those words interchangeably. And then we usually will take out a 1- to 2-centimeter rim of mesh that goes beyond the exposed area.
Q. And if there's not an erosion, but the patient's still suffering from pain, do you sometimes remove a larger section of the tissue and mesh?
A. We try to do what's called pain mapping, and then we try to focus on where that pain localizes to. And then if we can identify a problem there, for instance, the scar plate, as you mentioned, then that's the area we're going to focus on. So every one of these cases is a little bit different depending on what's the indication for revision.
Q. In your experience, what's been the average, if you can say size of tissue and mesh, that you've had to remove when the removal procedure is not related to an erosion, when it's more related to an ongoing pain complication?
A. I would say somewhere between 3 to 4 centimeters. You know, it'd be maybe like a square or a rectangle. Three by 4 centimeters would be a pretty extensive dissection.

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Q. Is it true that sometimes, in your experience, removing sections of the mesh and tissue that you decide you can't remove all the mesh you want in one procedure because it might be too invasive? Sometimes you may just do the anterior removal portion first; is that correct?
A. We try to focus on -- you're talking about a patient that has more than one mesh implanted in them?
Q. Yes.
A. We try to remove the one that's bothering them the most. And oftentimes it's hard to discern where their pain's coming from, but we tend to try to do the mapping and remove the mesh that's bothering them in that area. So that'd be very unusual if we would remove, say, more than one mesh in a single operation, yes.
Q. Do you have an opinion of whether or not mesh contracture or mesh folding can contribute to a patient suffering from ongoing pain?
A. I do.
Q. And what's your opinion?
A. Well, I think, as it states in the IFU, that mesh contracture can lead to pain and lead to having a revision. So there's contracture in

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surgery that we consider ordinary, say, up to 20 percent. Something more than 20 percent, especially if it's a 50 percent or 100 percent, then that's going to be more likely to cause pain.
Q. So you would agree that mesh contracture can cause pain?
A. I would agree with that, yes.
Q. And would you agree that polypropylene mesh through the foreign-body reaction process does, in fact, contract?
A. It can contract by a variety of different ways. That's one of them. But I believe that it's not so much the mesh that contracts, it's the soft tissue around the mesh that contracts.
Q. Through the healing process, through the foreign-body reaction, is that correct?
A. Yeah.
Q. And it's your opinion that that is actually warned about in the IFU?
A. Yeah, it is warned about in the IFU.
Q. And you think, appropriately so, it should be warned about in the IFU because that is a complication unique to mesh implants?
MR. KOOPMANN: Object to form.
A. You could have contracture with other

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surgeries, but I think that that's something that we are concerned about, maybe more concerned about with mesh.

Q. (By Mr. Bentley) Doctor, as we previously discussed, one of the benefits that you believe is associated with Prolift is the fact that it's more efficacious than native tissue repair; is that correct?

A. That is correct.

Q. I'm going to hand you what's being marked as Exhibit 3.

(Exhibit 3 was marked for identification.)

Q. And Exhibit 3 is a study by Stanford. Are you familiar with this study? I'll represent to you that it's, in fact, on your reliance list, but I don't believe it's cited in your report.

But my question was, are you familiar with Stanford's 2012 study?

A. I haven't read this recently. There's other articles that I'm probably more intimately familiar with, so . . .

Q. Okay. Using your criteria for evaluating whether a study has strength -- appropriate strength and weakness, would you consider this to be peer-reviewed literature?

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A. In the National Urogynecology Journal? Yes, I'm a reviewer for this journal. I publish in this journal. It is peer-reviewed material.

Q. It's a respectable journal; is that correct?

A. Yes, it's respectable.

Q. Okay. I just want to draw your attention briefly to the abstract. If you turn to the right-hand column about midway through, you can see where it says, "When similar outcome measures are compared, the published anatomic success rates of POP," that's pelvic organ prolapse, right?

A. Yeah. I'm sorry, where are you reading?

Q. On the second column on the right in the middle of that first paragraph.

A. Okay.

Q. Do you see where it starts, "...when similar outcome measures"?

A. I do.

Q. It says, "When similar outcome measures are compared, the published anatomic success rates of POP," or pelvic organ prolapse, "of anterior and apical compartmental surgery are similar for NT," or native tissue, "and MA," or mesh-augmented "repairs"; do you see that?

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A. I do.

Q. And so the author's essentially saying are, Hey, we think native tissue is as efficacious as mesh-related repairs.

Do you agree with that?

A. I agree that that's what the authors are saying. I don't agree with their conclusion, no.

Q. Okay. And in your report, you don't discuss this article, right?

A. Right.

Q. So there's no way for me to know why you disagree with this conclusion; is that fair?

A. No, there's no way for you to know.

Q. Could you tell me why you think this study is not reliable and you don't agree with the conclusions?

MR. KOOPMANN: Object to the form.

Q. (By Mr. Bentley) Strike that.

Do you think this study is reliable, or have an opinion one way or the other?

A. I don't have an opinion. I'm not that familiar with this study.

Q. But as you said, this is a reliable journal, correct?

A. Correct.

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Q. But you just disagree with the conclusions, correct?

A. I cite in my report the meta-analyses and the systematic reviews that I rely on, such as the Cochrane review, and the Cochrane review has a contrary result.

Q. Okay. So if the Cochrane review had looked at this article and come to the similar conclusion as Stanford, would that affect your opinion?

A. I'm not certain that the Cochrane review, at least the 2016, didn't look at this. The more recent Cochrane review by Maher may have included this. I'd have to go and read all the references in the Cochrane review to see if this was included.

Q. But my question is, if the Cochrane review reached a similar conclusion as to what Stanford did in 2012, namely the native tissue repair is as efficacious as mesh-augmented repairs such as Prolift, would that affect your opinions in your report?

A. No.

MR. KOOPMANN: Object to form.

A. It would not.

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Q. (By Mr. Bentley) Doctor, have you testified today extensively that you relied upon the Cochrane review?
A. Yes, I have.
Q. And if the Cochrane review changed their conclusion, that would not affect your opinion in this case?
A. I would have to read that report and see why they changed their opinions. I seriously doubt they're going to change their opinion based on one article.
Q. Sure. If they happened to, say, change their opinion based on more articles, would that further affect your opinion in this case?
A. I mean, if there's a greater level of evidence, then you're going to consider that more heavily.
Q. As you sit here, can you give me any reason as to why you discount the strength of this study?
A. It's not so much that I discount the strength of this, it's that I rely more heavily on other systematic reviews that are larger that included a greater number of studies.
Q. You rely more heavily on studies that

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support your opinion; is that correct?
MR. KOOPMANN: Object to form.
A. That works both directions. The studies that I rely on formulate my opinions. Those two things are interchangeable.
Q. (By Mr. Bentley) Right. But you don't present any argument or analysis as to why you think that this study by Stanford is any less credible than the studies that you rely upon that happen to support your opinion; is that fair?
A. Let's see. This is just one study. I'd be interested to see other studies like this, but I feel comfortable with the studies I've relied on.
MR. BENTLEY: Okay. I'm going to strike that as nonresponsive.
Q. (By Mr. Bentley) My question, Doctor, you don't present any argument or analysis as to why you think this study by Stanford is any less credible than the studies that you rely upon that happen to support your opinion; is that fair?
MR. KOOPMANN: Object to form.
A. That's fair.
Q. (By Mr. Bentley) I'm going to hand you what's being marked as Exhibit 4, which is a study by Iglesia.

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(Exhibit 4 was marked for identification.)
Q. And I think that Iglesia, again, is on your list materials but not cited in your report.
My question is, are you familiar with the Iglesia study?
A. Yes, I am.
Q. And is this from a respectable journal?
A. Yes, it is.
Q. Do you know of any problems offhand with this study?
A. I do.
Q. What are those problems?
A. I think the experience of Dr. Iglesia in terms of her ability to do a mesh-augmented repair has been called into serious question by a number of people. She's a very experienced native-tissue surgeon, a very inexperienced mesh surgeon. So I think if you take someone that's done thousands of native tissue repairs and compare the results with the first ten or twenty Prolift kits that they've done, the results are not going to be the same as what other more experienced mesh implanters would report.
Q. And Doctor, does that cut both ways, that an experienced surgeon with extensive

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experience in native tissue repair might be more successful at using native tissue repair as opposed to less-experienced surgeons with native tissue repair?
A. Yes. I think we get good at the operations that we do commonly and that we're comfortable with.
Q. And as we discussed, there are certain complications associated with a mesh-based repair that are not inherent in a native tissue repair; is that true?
A. Yeah, there's a few.
Q. And looking at the Iglesia study under the abstract on the first-page results, it states, "Sixty-five women were recruited from January 2007 to August 2009, when the study was halted due to predetermined stopping criteria for vaginal mesh erosion at a median follow-up of 9.7 months."
My question is, does that concern you, that this study was halted for meeting a -- for exceeding the threshold for erosions?
A. It does concern me that they were having more complications than what others had reported.
Q. And then in the "Conclusion" section there, it says, "At 3 months, there is a high

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vaginal mesh erosion rate (15.6%) with no difference in overall objective and subjective cure rates." And you disagree with that statement -- strike that.

"At 3 months, there's a high vaginal mesh erosion rate (3.6%) with no difference in overall objective and subjective cure rates."

My question is, that doesn't agree with your opinions in this case, does it?

MR. KOOPMANN: Object to form.

A. I used primarily the systematic reviews and Cochrane reviews to formulate my opinions, and this is of a lower level of evidence, and it doesn't affect my opinions.

MR. BENTLEY: And I'm going to strike that as nonresponsive.

Q. (By Mr. Bentley) My question was, the conclusions reached in this study are contrary to your opinions in this report, correct?

MR. KOOPMANN: Object to form.

A. It's contrary to some of my opinions.

Q. (By Mr. Bentley) And nowhere in your report do you discuss the weaknesses of this study; is that true?

A. That's true.

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Q. And nowhere in your report do you discuss the criticisms you have of Dr. Iglesia's ability to use a mesh-based implant; is that true?

A. Not in this report, but I did -- I have discussed that in other places, other people have, yes.

Q. Did you discuss that anywhere in your Prolift+M report?

A. No.

Q. Do you disclose that opinion of Dr. Iglesia's surgical ability anywhere in any of your reports in the mesh litigations involving Ethicon?

A. No.

Q. I'm going to hand you what's being marked as Exhibit 5. And this is a study by Dr. Diwadkar, dated 2009, from Obstetrics and Gynecology.

(Exhibit 5 was marked for identification.)

Q. And I believe this is another study that is, in fact, on your reliance materials but, again, not cited in your report.

My question, Doctor: Are you familiar with this study?

A. I don't have much familiarity with this

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study.

Q. And if you'll turn your attention, please, to the "Conclusion" section in the abstract, the authors conclude, the "Rate of complications requiring reoperation and the total reoperation rate was highest for vaginal mesh kits despite a lower reoperation rate for prolapse recurrence and shorter overall follow-up"; do you see that, Doctor?

A. Yes.

Q. And does that conclusion affect your opinions in this case?

A. No.

Q. Does that conclusion support or contradict your conclusions in this case?

A. My report doesn't have conclusions. My report is a number or a series of opinions that I've offered. I don't think it's a, like, a paper or a manuscript where I got introduction methods, results and conclusions. It's not written that way.

Q. Okay. Thank you.

In your report, you state one of your opinions is that Prolift is more efficacious than native tissue repair; is that correct?

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A. That's correct.

Q. And by efficacious, I mean that there would be less recurrence of the prolapse with the Prolift prolapse repair kit as compared to a native tissue repair; is that correct?

A. That's correct.

Q. Okay. And the conclusion here from these authors is stating that there's actually a higher reoperation rate with the vaginal mesh kits as compared to other surgical procedures; is that correct?

A. That's correct.

Q. And so my question is, this conclusion is actually contrary to your opinions reached in your report; isn't that correct?

A. That's correct.

Q. And in your report, do you discuss any reason as to why this study is any less credible than the other studies that you cite to in support of your opinion?

A. No.

Q. As you sit here today, do you have any reason to question the strength of this study?

MR. KOOPMANN: Do you want him to read it?

MR. BENTLEY: It's on his reliance list.

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He's already reviewed it. If you want to go off the record, I'm happy to --

MR. KOOPMANN: If you want to ask him specific questions about a document, then I think --

MR. BENTLEY: My question was --

MR. KOOPMANN: -- you ought to read it on the record.

Q. (By Mr. Bentley) As you sit here today, Doctor, do you have any understanding or appreciation of a reason why this study is any less credible than the other studies cited in your report in support of your opinion?

A. I'd have to go off the record and review the article, but as I sit here right now, I'm not that familiar with the article, so I can't criticize the article because I'm not familiar with it.

Q. But the article does reach a conclusion that's contrary to your opinion, right?

MR. KOOPMANN: Object to form; asked and answered.

A. Yeah, the conclusion here says that the rate of complications requiring reoperation was higher.

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Q. (By Mr. Bentley) Do you think patients would like to know that when they're deciding whether or not to undergo a surgical implant of the Prolift device?

A. Patients want to know what the risks and benefits of the procedure are. That's what we discuss with them every day when we do our informed consents.

Q. So is that a yes to my question, Doctor?

MR. KOOPMANN: Object to form.

A. Patients want to know risks, you know, so you have to gather that from as much information as you can collect. There's no way you can be aware of every single article in the medical literature.

Q. (By Mr. Bentley) But this article is actually on your reliance list, so presumably you are aware of it, correct?

A. I am, but some articles I'm more familiar with than others.

Q. And my question was, simply, patients would want to know that there may be a higher reoperation rate with Prolift mesh as opposed to other surgical techniques to treat prolapse; is that fair?

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A. That's fair.

Q. Doctor, would you be critical of Ethicon if they had warned of this increased risk in the IFU?

A. I don't have any criticisms for Ethicon in regards to the IFU.

MR. BENTLEY: I'm going to move to strike as nonresponsive.

Q. (By Mr. Bentley) My question, Doctor, is, would you have been critical of Ethicon if they had chosen to warn of this increased risk of reoperation in the Prolift IFU? Would you have been critical of Ethicon for including that information in the IFU?

A. I'm not -- I wouldn't be critical, no, they -- no.

Q. Would it be helpful for some doctors that weren't aware of this article to know that information when they were doing an informed consent with their patients?

MR. KOOPMANN: Object to form.

A. I don't think it'd be helpful.

Q. (By Mr. Bentley) You don't think it'd be helpful for some doctors to know there's a higher risk of reoperation with Prolift-based

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repairs as compared to other surgical procedures?

A. I think I've already answered that question, but I think, again, you have to go through the risks and benefits of the procedure. What I discuss with patients is that the benefit of the graft-augmented repair is, in my opinion and that of many others in the systematic reviews like the Cochrane review, is that you get a better subjective and objective cure rate. There is a higher risk of graft exposure when you're using a graft, whether it's mesh or a biological. You're going to have potential for healing abnormalities. I discuss that with patients, yes.

MR. BENTLEY: I'm going to strike as nonresponsive, Doctor.

Q. (By Mr. Bentley) My question, specifically, though, is, the information based in this study that indicates that there's a higher reoperation rate with Prolift-based repairs, do you think that would have been helpful for doctors to know to inform their patients during the risk-benefit discussion so they can get informed consent as to the procedure to implant a Prolift device?

MR. KOOPMANN: Object to form.

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A. No, I don't think this article would have been helpful to them.
MR. KOOPMANN: Can we go off the record for a second?
(Discussion held off the record.)
Q. (By Mr. Bentley) Doctor, is the risk of reoperation a serious risk for patients?
A. Serious risk?
Q. Yeah, that was a bad question. Sorry.
Are there risks inherent with any surgery?
A. Yes.
Q. And so having an additional surgery presents additional risks; is that correct?
A. Having a reoperation?
Q. Sure.
A. Yes.
Q. And likewise, not having a reoperation is probably safer than having a second surgery. Would you agree with that?
A. It would depend on the particular disease. Some people need a reoperation. If they don't, then their health made be, you know, more in harm than not having the reoperation. You have to look at each patient individually.
Q. Right. And we're here discussing

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Prolift and prolapse, which, I'm sure you're aware, having a second surgery in the pelvis to treat recurrence of prolapse -- is that a good idea or a bad idea, generally?
A. Having a second surgery to reoperate for prolapse?
Q. Yeah.
MR. KOOPMANN: Object to form.
A. That's something we generally try to avoid. That's what we're trying to do here by using a graft-augmented repair.
Q. (By Mr. Bentley) And the study that we just looked at showed that there's a higher risk of reoperation using the mesh-based repair kit, right?
A. In this study, yes.
Q. Doctor, I'm going to hand you what's being marked as Exhibit 6. And this is an article by Dr. Ridgeway in the American Journal of Obstetrics and Gynecology.
(Exhibit 6 was marked for identification.)
Q. And this is, again, on your reliance materials and not cited in your report.
My question is, are you familiar with this study?
A. Yes, I'm familiar with this study.

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Q. And if you'll turn to the fifth page, you can see the "Clinical Implications" section. Are you with me? It'll be the last page. And under "Clinical Implications" on the last page, it states, "Transvaginal mesh plates with prolapse kits can lead to debilitating complications such as chronic pain, dyspareunia, symptomatic mesh erosion, and vesicovaginal fistula that may require extensive mesh excision"; did I read that correctly?
A. Yes.
Q. And would you agree that those are potential complications with using transvaginal mesh-based repair kits such as Prolift? Would you agree with that statement?
A. Yes.
Q. And the second clinical implication is, "Surgeons who place transvaginal mesh using prolapse kits may be unaware of complications because most patients seek care from a different physician"; did I read that correctly?
A. Yes.
Q. And I believe you've testified, actually, that you treat complications from other surgeons who have implanted products; is that

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correct?
A. Yes.
Q. And so sometimes maybe the other doctor might not know about the complication; is that correct?
A. A small percentage. I would say most of the time the referrals I receive from other doctors are from the implanting surgeon.
Q. Okay. So do you agree or disagree with this second clinical implication that we just reviewed, that sometimes surgeons may not know that their patient had complications?
A. Well, sure, there might be a few patients here or there that you might not be aware of, but I think the overwhelming majority of patients and surgeons are still connected.
Q. Right. And so this leads to the reason of why you probably want to warn about things in the IFU so everyone can have full knowledge. Would you agree with that?
MR. KOOPMANN: Object to form.
A. I think the IFU is adequate, and I think there was enough warning there.
MR. BENTLEY: I'm going to move to strike as nonresponsive.

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Q. (By Mr. Bentley) My question was, because of this clinical implication that some surgeons don't know about their complications, would you agree that it's reasonable to include the complications associated with Prolift in the IFU so that all the doctors have all the information available to them? Would you agree with me that that's reasonable?

MR. KOOPMANN: Object to form.

A. No, I don't -- I don't agree with the statement.

Q. (By Mr. Bentley) So you don't think it's a good idea to put all of the complications associated with Prolift in the IFU?

A. I think that the complications that are stated in the IFU are adequate. I think there's enough information on complication data there.

Q. Do you know if the IFU cites any specific data?

A. Does it cite specific data? It lists, it itemizes potential risks, but IFUs are not heavily referenced.

Q. So there's no specific data citing the IFU?

A. I'd have to look at the Prolift IFU to

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be certain, but I'm not aware of major references in the IFU. In the Prolift monograph, certainly there's plenty of references of complications and information that surgeons should be aware of.

MR. BENTLEY: I'm going to strike after "references in the IFU."

Q. (By Mr. Bentley) Doctor, are you aware of any regulation or law that prohibits Ethicon from adding evidence or data to the IFU?

A. Each time evidence is added to the IFU, my understanding is that the IFU then has to go back through the regulatory and get approved again. So it's not an easy process to add or subtract things from an IFU.

Q. It's your testimony today that the IFU gets approved by the FDA?

A. Maybe "approved" is not the right word, but it's reviewed, you know, by regulatory agencies. The IFU is a public document.

Q. Does the FDA have authority to force a medical device manufacturer such as Ethicon to change their IFU?

MR. KOOPMANN: Object to form.

A. I don't know the answer to that.

Q. (By Mr. Bentley) And you don't know if

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the FDA approves IFUs?

A. I know they require an IFU. I don't know how much it goes beyond that to say if this was adequate or written properly.

Q. And you don't know if there's some law or regulation prohibiting Ethicon from, say, adding risk rates to the IFU to better inform doctors and thereby facilitate the informed consent process?

A. I'm not aware of, one way or the other.

Q. Would you be critical if Ethicon added more information to the IFU such as maybe complication rates?

MR. KOOPMANN: Object to form.

A. I don't have an opinion on that either way.

Q. (By Mr. Bentley) Would that have been helpful for some doctor, do you think?

A. Not necessarily.

Q. Why don't you think it'd be helpful?

A. I don't think a lot of physicians read the IFU. And with that said, I think people rely more on their education, their training, what they've learned from colleagues and courses, so I think the IFU's one of many things they rely on, but I don't think it's the top of the list.

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Q. Do you in your personal practice review the IFU?

A. I do.

Q. How frequently do you do that?

A. I do that on all new products that I use. And if there's a change to the IFU, then I would re-review it.

Q. How do you become aware if there's a change to the IFU?

A. Various ways. It might be reported to me by some representative from that manufacturer. I may get a written correspondence or an e-mail --

Q. So unless --

A. -- or it might be some personal communication between me and one of the representatives.

Q. So is it your testimony today that you review an IFU when you're encountering new product or when some representative from the company tells you there's been a change? Is that your testimony?

A. That's my testimony.

Q. Doctor, do you believe that there's been an evolution in understanding of the complications associated with polypropylene prolapse repair kits such as Prolift?

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A. I do.
Q. And what do you think the evolution has shown?
A. I think it's an evolving material science. There's new information that's discovered and looked at and reviewed.
Q. And has the science shown that maybe larger pore, lighter weight mesh is associated with reduced complications?
A. The data's very mixed.
Q. Do you have any understanding as to what the purpose for -- or what the purpose was of Prolift+M?
A. The goal of Prolift+M was to leave less foreign body behind in the patient.
Q. And that has a clinical -- that has clinical significance to you, correct?
A. Potential.
Q. Okay. And what's the potential clinical significance of leaving less foreign body mesh material in the body?
A. The idea of having less foreign body would be less foreign-body reaction, and that there would be less pain or exposure associated with the device.

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Q. And from your experience, do you think that that is, in fact, true?
A. No, it's not true. In my experience, it was something that seemed very intuitive, but the literature has not shown that.
Q. So you don't think there is any benefit to using Prolift+M that left less mesh and foreign body in the patient's body?
A. The systematic reviews and the retrospective studies don't show that, so the complication rate between Prolift+M and Prolift were not significantly different.
Q. So there's no benefit to using Prolift+M as opposed to Prolift?
A. I don't see any benefit.
Q. Okay. But in your practice, you switched away from using Prolift to Prolift+M; is that correct?
A. That's correct.
Q. I'm just not understanding. So why would you switch to a new product if there's no benefit?
A. As I mentioned earlier, I'm an early adopter of new products. And intuitively, it seemed like it would be a good idea, looking at the

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Ultrapro data from hernia surgery, and so it was something that many surgeons were attracted to. We tried it. I did about a hundred of each, and then the Pro product was no longer being offered, but at least, when preparing this Prolift and Prolift+M report, my review of the literature, my own personal experience is I didn't see a clinical significant difference between how the two products performed in terms of efficacy or safety.
Q. So do you think there's better data associated with Prolift versus Prolift+M?
A. There's certainly -- Prolift is a much more widely studied product. There was a greater number of articles to review and systematic reviews.
Q. So taking that into account, and taking into account your testimony that there's no benefit to Prolift+M, why would you use Prolift+M today if it was still available?
A. I don't think that was my testimony. My testimony was I think I would use either product, Prolift or Prolift+M, if either of them was still available, because they were equivalent products. So there are patients that I feel would be ideal for either of those products.

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Q. If there's no benefit to Prolift+M, how can you decide if a patient's ideal for Prolift or Prolift+M?
A. What I mentioned is I would be pleased with either product. They're both good products. They were equivalent, according to the literature and according to my own personal experience, so I'm not saying I favor +M over Prolift. If you ask the question in reverse, I would be just as pleased to have used Prolift, you know, last week or -- you know, compared to +M.
Q. Even though Prolift had more data available?
A. Prolift had more data, but I think there was enough data available on +M, and I had enough personal experience with +M, to feel that it was at least performing equally.
Q. Doctor, do you think that mesh contracture is a clinically significant complication for the patient?
A. It would depend on the degree of contracture.
Q. Can mesh contracture be a clinically significant outcome for a patient?
A. It can be.

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Q. And that could lead to maybe revision surgery where you have to remove part of the mesh?
A. Correct.
Q. Do you have an understanding of how mesh contracture leads to pain for a patient?
A. I think that the theories -- there's a number of theories that have been proposed, one of which is that the contracture can lead to, you know, an exaggerated foreign-body response. And so if someone has a sensation that they have a foreign body in them, then that's going to cause pain.
Q. It's your testimony that a foreign-body response is essentially what the pain is that a patient's experiencing?
A. No, I mentioned that -- you asked me if -- how contracture can cause pain.
Q. Right.
A. And I said that's one of the factors. Contracture can cause pain by eliciting a foreign-body response.
Q. Is there any other way that you know of that contracture can cause pain?
A. Yes.
Q. How is that?
A. Well, the scar plating that was

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mentioned earlier in the deposition. The scar plating can lead to a stiff area in the vagina that can cause pain. It could also place soft tissue under tension, and soft tissue under tension can cause pain.
Q. Could it also entrap nerves, for example?
A. I'm not aware of that. There may be some potential for it, but I have not seen that clinically personally, or seen that in the literature.
Q. Can mesh contracture also lead to dyspareunia?
A. Yes.
Q. Can mesh contracture also lead to painful intercourse for a woman's partner?
A. Yes.
Q. And mesh contracture can lead to shortening of the vaginal canal?
A. Yes.
Q. In your experience, how would you treat a patient suffering from the serious complications we discussed associated with mesh contracture? In your experience, how would you approach treating that patient?

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A. Well, there would be a variety of ways. The first thing we'd start off with is vaginal estrogen to try to soften the vaginal mucosa to make it more supple.
Second treatment would be pelvic floor massage or physical therapy to try to reduce the muscle from being under tension. Oftentimes it's really just tension, not contracture; it's hard to separate those two things, and they can happen independent of each other.
And then if the nonoperative management doesn't work, then one can consider revision surgery.
Q. Is it your testimony that treatment with estrogen cream can improve mesh contracture where there's not an erosion present?
A. "Mesh contraction" may be too specific of a term. It's hard to separate. When I see a patient that has a mesh implant regardless of an exposure or no exposure that has pain, if the mucosa feels thin over the graft material, then we're going to prescribe vaginal estrogen.
Q. Can estrogen cream treat a hardened scar plate?
A. No.

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Q. When there's no erosion present but a patient's still suffering from pain, can estrogen cream treat that pain?
A. It can treat vaginal atrophy and dryness. That may be contributing to the pain. Most of the pain is multi-factorial.
Q. Isn't it true that usually you have to treat those types of complications with surgical intervention?
A. No, that's not how I would describe it.
Q. In your experience, Doctor, have you seen situations where the mesh can become infected?
A. Have I seen infected mesh?
Q. Yes.
A. Yes.
Q. And, in fact, do you have a theory that infection leads to pain?
A. I think it's one of many theories, but yeah.
Q. Do you not hold that theory anymore?
A. No, I do hold that theory. It's a theory that others have proposed. I've read that in the medical literature.
Q. Is there some reason why you don't discuss that potential complication in your report

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in this case?
A. I believe I discussed it in my TVT report, but I don't see that I discussed it here in the Prolift report.
Q. Do you think that the theory that mesh infection leads to pain is applicable to the Prolift implant?
A. Yes, I do.
Q. Do you think that would be important for patients to know that's a potential complication?
A. That's a complication we discuss with patients with every surgery we do, the risk of infections.
Q. You discuss the potential for infection-related pain with your patients?
A. I mention to them any time I place a foreign body, that the foreign body can potentially become infected, whether that's silicone or polypropylene, whatever the implant is.
Q. And do you discuss that you have a theory that the infection leads to pain?
A. I discuss with them the consequences of infection, pain being one of them, mesh revision being another one, so it's one of many reasons why one would revise an implant.

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Q. Do you think that's information that would have been helpful to be in the IFU?
MR. KOOPMANN: Object to form.
A. I believe it's in the IFU. I think infection is discussed in the IFU.
Q. (By Mr. Bentley) Is the clinical significance of infection which causes pain in the IFU?
A. Now you're connecting a lot of thoughts there, so I don't think it's written in that manner, but I think it's reasonable knowledge that most surgeons would understand, that infection can cause pain.
Q. Would you have been critical of Ethicon for putting that information in the IFU?
A. No, I wouldn't have been critical.
Q. Doctor, I'm going to hand you what's being marked as Exhibit 7.
(Exhibit 7 was marked for identification.)
Q. And there is a paper by Terlecki and yourself published in the AUA Update Series '10. I'm sure you're familiar with this -- presumably familiar with this article. It's listed on your reliance materials, but, again, it's not listed in your report.

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My question is, why don't you discuss your own article discussing these very issues in your report?
A. This article here was an overview of the controversy of incontinence and prolapse surgery, so this article was in response to the FDA Public Health Notification. And I was solicited by the American Urologic Association to write this article to help urologists understand what was in the FDA PHN. So that's why this was written. This is something that I didn't rely on for this Prolift report because this is not specific to Prolift.
Q. The title of the article is, "The Use of Surgical Mesh for Incontinence and Prolapse Surgery: Indications for Use, Technical Considerations and Management of Complications"; is that correct?
A. That's correct.
Q. And Prolift is a surgical mesh kit that's used for treatment of prolapse, correct?
A. Correct.
Q. So this article deals with the very issues that you discuss in this report; isn't that correct?
A. That's correct.

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Q. Do you stand by your words in this article that you're a co-author of?
A. I do, but again, this is similar to the Urology Times article. The AUA updates are a lower level of evidence. They reflect my opinions. This is not a peer-reviewed publication. The AUA update series is not something that's published. It's available to members of the American Urologic Association.
Q. Right. But you stand by your words in this article, right?
A. Yes, I do.
Q. If you could please turn to Bates number 0764, or on the article, it says page 133.
A. Okay.
Q. On the left-hand column, talking about complications, about halfway down, it says "Vaginal Wall Extrusion," and then in bold you write, "Vaginal wall extrusion occurs more commonly with a reinforced synthetic repair than a biological repair"; did I read that correctly?
A. Yes.
Q. And you still think that; isn't that true?
A. I do.

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Q. That's what the evidence shows; isn't that correct?
A. That's correct.
Q. And do you discuss that with your patients?
A. I do.
Q. And do you think Ethicon should have warned about that in the IFU?
MR. KOOPMANN: Object to form.
A. Are you asking me if Ethicon should have compared and contrasted their products to other people's products in their IFU?
Q. (By Mr. Bentley) Well, if you know and Ethicon was aware that there's a higher risk of erosion with Prolift as compared to other repairs, do you think that would have been helpful information to include in the IFU?
MR. KOOPMANN: Object to form.
A. I don't believe that's the purpose of the IFU, so no.
Q. (By Mr. Bentley) Remind me. What's your idea of what the purpose of the IFU is.
MR. KOOPMANN: Object to form.
A. The purpose of the IFU is to make a reasonable surgeon aware of unique complications,

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and maybe more common complications, describe organs that can be injured, the things that we mentioned earlier in the deposition. And I believe mesh extrusion is listed in the IFU, so I believe that's adequate.
Q. (By Mr. Bentley) Okay. On the next column over, middle of the page, bolded, it says, "Patient factors that may lead to an increased risk for extrusion include age, estrogen status, prior radiation, active vaginal infection, smoking, obesity, immunosuppression, diabetes and concomitant hysterectomy"; did I read that correct?
A. Correct.
Q. And do you still hold that opinion?
A. I do.
Q. Do you know if that information's conveyed in the IFU for doctors?
A. I don't believe so.
Q. Do you think it would have been helpful for doctors to know that there are certain patient factors that may affect the risk for extrusion?
MR. KOOPMANN: Object to form.
A. These factors that are listed are factors that would affect any wound healing, and so this is common knowledge. I think any reasonable

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surgeon would understand someone who has immunosuppression, diabetes, smoking, these are risk factors for healing abnormalities. They're not unique to polypropylene mesh. And so I believe a reasonable surgeon would understand these risk factors.
MR. BENTLEY: I'm going to move to strike as nonresponsive.
Q. (By Mr. Bentley) Doctor, my question was, simply, do you think that this information would have been helpful for doctors to have in the IFU?
MR. KOOPMANN: Object to form.
A. No, I don't. I don't believe it would be helpful.
Q. (By Mr. Bentley) Going down to the next paragraph, in bold, you continue, "Any adverse mesh implantation features that can be mitigated preoperatively should be addressed before stress urinary incontinence or pelvic organ prolapse surgery." Do you agree with that?
A. I do.
Q. Do you think it would have been helpful for Ethicon to tell doctors how they can mitigate complications preoperatively?

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A. No, I don't think that was Ethicon's responsibility.
Q. You don't think it's Ethicon's responsibility to inform doctors how to decrease potential complications and increase the efficacy of the products that it sells to be permanently implanted in women's bodies?
MR. KOOPMANN: Object to form.
A. I think it's the job of the professional medical societies and the responsibility of the physician to be educated properly on basic fundamental surgical knowledge.
Q. (By Mr. Bentley) So you don't think Ethicon should share information it's aware of regarding how to decrease complications or increase efficacy of its products?
MR. KOOPMANN: Object to form.
A. No, I think the information would have been redundant.
MR. BENTLEY: Move to strike after "No."
Q. (By Mr. Bentley) Further down on the page under "Urinary tract erosion," it states -- strike that.
Future down the page under "Urinary tract erosion," you state, "A rare but dreaded

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complication of graft-based stress urinary incontinence and pelvic organ prolapse surgery is erosion into the bladder, urethra or rectum. The complication can occur regardless of graft composition but is certainly more common with synthetic material"; did I read that correctly?

A. Yes, you read that correctly.

Q. Do you still hold that opinion?

A. I do.

Q. Do you know if that's included in the IFU?

MR. KOOPMANN: Object to form.

A. I think that it warns about risks to surrounding structures, including bladder, urethra and the rectum, and so it mentions about perforation of visceral structures, et cetera, so yes, I think it's mentioned in the IFU.

Q. (By Mr. Bentley) Does the IFU convey the severity of that complication as you state in your paper?

A. No, that's not the role of the IFU.

Q. Turning to the next page, on the right column towards the bottom of the page under "Complications unique to mesh kits," you state, in bold, the second sentence, "Disadvantages of a kit

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include the expense, blind needle passage, unfamiliarity of procedure steps, and potential for marketing to inexperienced pelvic surgeons who may overestimate the usefulness of the kit"; did I read that correctly?

A. Yes.

Q. Do you still hold that opinion?

A. I do.

Q. In your report, have you explained how that opinion affects the risk-benefit profile of the Prolift product?

A. I'm not certain what you're asking me there.

Q. That was probably a bad question.

In your report, do you discuss this opinion discussing the disadvantages of a mesh kit that are unique to the mesh kit? Do you discuss all of those complications in your report?

A. I don't believe I discuss expense in the report. Unfamiliarity of procedure steps, I don't itemize all those, no.

Q. Would those complications associated with a mesh kit also be applicable to Prolift+M kit?

A. Any surgical kit.

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Q. Is that a yes?

A. Yes.

Q. On the next page, Doctor, the bottom is 135, in the column on the right, the second bolded sentence says, "We have noticed an escalation in the severity of such complications and have had to adopt an increasingly complex and aggressive approach to these healing abnormalities. Our salvage protocol is designed to manage complex graft complications and prevent the need for a reoperation"; did I read that correctly?

A. Yes.

Q. And does that refer to what we discussed earlier about the escalation of understanding of the complications associated with mesh-based repairs for prolapse?

A. I don't believe we've discussed escalation earlier.

Q. Has there been an escalation in the severity of such complications, as you state here in this paper?

A. It's hard to say. I certainly have seen a number of complications in my practice. I don't know if that is reflective of the referral nature of my practice, being in one location for a longer

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time. It's hard to say. But, you know, we saw an increase in the number of complications. That's something that I've reported on up until around 2011, 2012 when we began to see a plateau. And we continue to see that plateau. So the number of complications that I've been managing for the last four to five years has been relatively stable.

Q. And Doctor, my question is, Doctor, in your report, do you discuss your statement here that you've seen an increase or an escalation in the severity of such complications? Do you discuss that in your report?

A. No.

Q. Is there any reason why you didn't discuss your observation that there's been an increase or an escalation in the severity of mesh-related complications in your report?

A. As I mentioned earlier, the report is specific to Prolift and Prolift+M. It's not specific to management of transvaginal mesh complications.

Q. You don't think that management of Prolift-related or Prolift+M-related complications is relevant to your opinions in your report?

A. I think it's relevant, but I don't think

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that's the focus of the report.
Q. You don't think the severity of complications in the attendant revision surgery affects the risk-benefit profile of the Prolift or Prolift+M medical device?
A. I believe I've discussed the risk-benefit profile in the report.
Q. But in -- I'm sorry. Go ahead.
A. So I'm comfortable with what I have reported here. I have an entire section overviewing complication prevention and management. If you look on page 30, "Complication Prevention Management," so I feel that this report is adequate and comprehensive. There's a section on safety of the product. That includes three to four pages on safety. The clinical data summary on page 32 has a table that I cut and paste from the Prolift monograph, including information on various complications, the total of the complications, the number of patients in these studies. So I believe that this report is quite adequate in commenting on complications.
Q. My question wasn't in any way about the adequacy of your report.
My question was, simply, do you feel that

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this statement, your words from your 2010 paper that you've seen an escalation in the severity of mesh-related complications, does that affect the risk-benefit profile of the Prolift mesh implant to treat prolapse?
A. No, I don't believe so.
Q. You don't think the severity of complications affects the risk-benefit profile of a medical device?
A. That's a complex statement, but I think that what I mentioned earlier is that I believe that that escalation that I was witnessing was just reflective of the referral network that I had developed, so these complications were being referred to me. And in retrospect, I think that was what was happening. I don't think the complications were happening more commonly, or the incidence or prevalence was changing in any way, it was just where the patients were being referred to and the willingness of physicians in the local community to manage these patients.
Q. So it's your testimony that you weren't aware of the escalation and severity of mesh complications until you happened to be referred some patients in your personal clinical practice?

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A. I was aware of the complications. I think the choice of the word "escalation" was a poor choice of words, really, on my part.
Q. In the next sentence, you talk about your salvage protocol.
Do you discuss your salvage protocol with patients when you're giving an informed consent as to whether to implant a meshed-based repair?
A. No. As I mentioned earlier, I focus on the implant surgery and the risks and benefits of that surgery. I don't talk about subsequent surgeries.
Q. So in your discussion of risks, you don't think it's relevant to discuss that you have to use a mesh -- strike that.
In your discussion of the risks in doing informed consent with a patient, you don't think it's relevant to discuss the severity of the revision surgery that you've termed a "salvage protocol"? You don't think that's relevant in the risk-benefit discussion?
MR. KOOPMANN: Object to form; compound, asked and answered.
A. I don't think it's a benefit. And I didn't come up with the term "salvage protocol."

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Q. (By Mr. Bentley) But this is your paper, right?
A. It is, but the word "salvage" you'll see repeatedly in the medical literature. Dr. Jerry Blaivas uses that word. A number of people use that word when describing the use of the pubovaginal sling. Some people use the word "terminal procedure." It has a lot of words that are attached to it, but "salvage" is not a word that I came up with.
Q. But it's bolded in your paper, right?
A. It's bolded in my paper.
Q. Okay. On the next page, Doctor, if you could look at the left-hand column of page 136, the second bolded section, you state, "However, dyspareunia and pelvic pain can occur in complete absence of extrusion, erosion or infection. In these cases, it is thought to be due to tension on the graft, graft contracture, superficial graft placement or nerve injury."
Do you still hold that opinion, Doctor?
A. Yes, that's the opinion I just stated earlier in regards to graft contracture and tension, and muscle under tension, et cetera.
Q. And those are indeed complications that

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can happen with the Prolift or Prolift+M implant; isn't that correct?
A. Correct.
Q. Yet, in your report, the only unique complication I believe you discuss is mesh exposure.
Is there any reason why you don't detail these other complications in your report as unique complications to the Prolift or Prolift+M?
A. I believe I discuss more than that in the report.
Q. Okay. Turn to page 26 of your Prolift report discussing the IFU. In that first paragraph under Section A, you have a sentence that states, the IFU, "It warns of the only unique complication with the device," and you have a dash, and it says, "mesh exposure"; do you see that?
A. I do.
Q. Is there any reason why you didn't discuss the other complications we just reviewed in your paper from 2010 in your report in this case?
A. Well, because I was trying to separate complications that are unique to the graft versus complications that occur with ordinary urogynecologic surgery. So if you do a native

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tissue repair, you can end up with contracture in the vagina. You could end up with muscle under tension, superficial sutures. Certainly you can entrap the nerve when doing procedures like sacrospinous ligament fixation. So again, I'm just trying to separate the -- what's unique to the graft material versus what's not unique.
Q. Is there a unique foreign-body response profile to the polypropylene mesh used in Prolift as compared to native tissue repair?
A. Yes.
Q. And you don't discuss that in your report; isn't that correct?
A. I think mesh exposure can happen by foreign-body response. Mesh exposure can occur by a variety of different mechanisms, but that's one of them.
Q. And you don't discuss that in your report, isn't that correct, the unique foreign-body response to polypropylene or Prolift-based prolapse repair?
A. I'm not certain if I used the word "unique," but I believe there's an entire section looking at inflammation after Prolift, claims of cytotoxicity, claims of degradation, the risks and

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benefits, so there's quite a bit in those sections. And I think that those sections outline the potential foreign-body response.
Q. Your summary in your paper on -- your summary in Exhibit 7, your 2010 paper, towards the end of that paragraph in bold, you state, "Therefore, reinforced pelvic floor repairs should only be performed in well-selected patients after they provide informed consent." Does that apply to Prolift implants? Is Prolift a mesh-based pelvic floor repair?
A. This report was written in 2010, so it would apply to patients going forward that would have a reinforced repair after the FDA Public Health Notification and after, you know, ten or so years of experience with pelvic floor kits.
Q. So you think Prolift or Prolift+M would still be appropriate in carefully selected patients?
A. In carefully selected patients, yes.
Q. Do you think the IFU should have maybe conveyed that information that Prolift is only appropriate in well-selected patients?
MR. KOOPMANN: Object to form.
A. When the IFU was written, I think it did

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a good job at the time in detailing the risks and benefits. No one really knew at the time who the right -- who was the perfect, you know, correct patient, properly selected patient or that well-selected patient.
Q. (By Mr. Bentley) But as more information was collected and as you came to know more about which patients this was more appropriate for, that information should have been conveyed in the IFU; isn't that correct?
MR. KOOPMANN: Object to form.
A. No, that's not correct.
Q. (By Mr. Bentley) You don't think it's helpful for Ethicon to tell doctors which patients are appropriate for implantation of its medical devices?
MR. KOOPMANN: Object to form.
A. I don't think that's Ethicon's responsibility. I think it's the responsibility of professional medical societies and the responsibility of the individual.
Q. (By Mr. Bentley) Do you think that it's Ethicon's responsibility to inform physicians how to safely use its products?
MR. KOOPMANN: Object to form.

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A. I think it's to inform them how to safely use their products. That goes back to the IFU. I think the IFU is one of many mechanisms that are used to inform patients and physicians -- I'm sorry, to inform physicians on the product, but it's not the only -- the only piece of information.

Q. (By Mr. Bentley) And that wasn't my question.

My question is, do you think that it's Ethicon's responsibility to inform physicians how to safely use its products?

A. Yes.

Q. And if Ethicon had some information that it knew would help physicians use its products more safely, Ethicon should have shared that information with those physicians, correct?

MR. KOOPMANN: Object to form.

A. I believe they did share the information, as much information as they had. It's reflected in the Prolift monograph and other efforts that they made to share information with the physicians.

Q. (By Mr. Bentley) And is it your testimony that all the information shared in the monograph is also in the IFU?

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A. No, the monograph is a much longer document. It's a supplement to the IFU.

MR. BENTLEY: Can we take a short break?

MR. KOOPMANN: Sure.

(Recess taken from 4:07 p.m. until 4:21 p.m.)

Q. (By Mr. Bentley) Doctor, we're back from a short break. Are you ready?

A. Yes.

Q. If you could please turn back to what we marked as Exhibit 3, it was a Stanford study from 2012. And if you could turn to page 24. The page number's in the top left corner.

A. Yes.

Q. On page 24, on the right-hand column, there's a section titled "Anterior compartment"; do you see that on the right-hand column?

A. Yes.

Q. The second paragraph starts, "A careful review of publications looking at success for anterior colporrhaphy reveals that for many years, the reported primary outcome for successful treatment was the correction of stress urinary incontinence."

Have you ever read any data or seen a study

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that suggested that?

A. I'm not reading that. Were you reading the first sentence?

Q. The second paragraph, "A careful review of publications looking at success for anterior colporrhaphy reveals that for many years, the reported primary outcome for successful treatment was the correction of stress urinary incontinence"; did I read that correctly?

A. Yes.

Q. Okay. And were you aware that many of the studies discussing the success of native tissue were actually looking at whether the prolapse successfully treated for a correction of SUI?

A. Yes, the Kelly plication, for instance, was a repair that was done for stress urinary incontinence.

Q. Were you aware -- I'm sorry. Go ahead.

A. Yes, so I was aware of that, yes.

Q. Were you aware that that would have reduced the overall success rate attributed to native tissue repair for recurrence of prolapse as opposed to prolapse and stress urinary incontinence?

A. I am aware that some of that was

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included. How it affected it, I don't -- I'd have to review each article to see if it had lower outcomes and pull the average down.

Q. Okay. And you haven't performed that analysis, right?

A. I have not.

Q. If you turn to page 25, the "Conclusions" section, under the first paragraph under "Conclusions," the last sentence states, "The overall success rates of native tissue and mesh augmentation repairs when recurrent prolapse is the primary outcome measure are very similar"; did I read that correctly?

A. Yes.

Q. And do you have an opinion as to whether or not that statement is correct?

A. I do.

Q. And what's your opinion?

A. That it's not correct.

Q. But you haven't performed the reanalysis that you just previously testified that you would need to do to know whether or not these statements are correct, fair?

A. I don't need to perform it. It's been performed in the Cochrane reviews and other

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reviews. Those reviews adjust for these sort of variables. That's the strength of systematic reviews. So it can adjust for these minor details.

Q. Okay. And if you turn the page, please, to page 26, at the top, the second sentence states, "One recent prospective randomized study reported no difference in the mesh augmentation and native tissue groups, but the study was stopped early due to a high incidence of mesh erosion/exposure (15%)." And that refers to footnote 78. If you'll turn to footnotes, you'll see that footnote 78 is, in fact, the Iglesia study that we previously looked at; is that correct?

A. That's correct.

Q. And so that's another study showing that, in fact, native tissue repair is similarly efficacious as mesh-augmented repair; is that correct?

A. We've already been through that study.

Q. Right. Doctor, I'm going to hand you what's being marked as Exhibit 8.

(Exhibit 8 was marked for identification.)

Q. And this is a study from a number of people. The first author is Velemir. And I believe this is also on your reliance list and not

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discussed in your report.

My question is, are you familiar with this study?

A. I have some familiarity with this study. I'm familiar with the work of Dr. Jacquetin. I believe he did a lot of the original Prolift studies.

Q. He was, in fact, part of the original French TVM group that came up with the Prolift device; is that correct?

A. I believe he was part of that group, along with Dr. Clave and others.

Q. Okay. And Dr. Clave's published on foreign-body reaction to the mesh; is that correct?

A. That's correct.

Q. And what level of mesh contracture would need to exist for you to determine that it's clinically significant, approximately?

A. What I've seen reported in various articles is 20 percent or more.

Q. 20 percent or more of mesh contracture would lead to clinically significant outcomes; is that correct?

A. Potentially, yes.

Q. If you could turn to page -- I don't see

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page numbers, so it would be the second-to-last page of Exhibit 8 that we're looking at.

A. Where there's some pictures?

Q. Yes.

A. Mm-hmm.

Q. In that first paragraph on the left-hand column, in the bold, they state, "They compared the initial length of the implanted mesh and sonographically measured mesh length 6 weeks postoperatively, observing a decrease in the mesh length of 60%"; do you see that?

A. I do.

Q. And this is from, actually, the creators of the Prolift product; is that correct?

A. Well, I don't know the other authors besides Jacquetin.

Q. Okay. If you would turn to the second page of the article, on the left-hand column, the first full paragraph starts, "Between 2000 and 2005 our team participated in the development of the tension-free vaginal mesh technique. Over time it appeared that mesh retraction was probably a contributing factor to recurrence, postoperative pain and dyspareunia"; do you see that?

A. I do.

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Q. And do you think that it's of importance that the creators of this technique are actually reporting on mesh contracture leading to these complications? Is that important to you?

A. Well, yeah, it is important to me.

Q. And is it important to you that these authors are reporting that they're observing up to 60 percent mesh contracture with the Prolift technique that they came up with?

A. I don't know if they're using the word "contracture." They talk about a decrease in mesh length of 60 percent anterior meshes. It just says "decrease in length." They don't say how that happened.

Q. Is that important to you, Doctor?

A. A decrease in length?

Q. Right.

A. Yes, that's important.

Q. And that's above your 20 percent threshold; is that correct?

A. That's correct.

Q. And do you think that it would be important for doctors to know that the inventors of the Prolift technique who observe mesh shrinkage or contracture of up to 60 percent of the overall

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length -- would that be important for doctors to know?
A. Yes.
Q. Would that maybe affect the informed consent process when discussing risks and benefits of this product?
A. No.
Q. Doctor, do you know when Prolift and Prolift+M were pulled from the market?
A. I don't believe they were ever pulled from the market. I believe that Ethicon stopped offering the product sometime around 2012.
Q. And you've testified that if these products were still on the market, you'd still be implanting them today; isn't that correct?
A. That's correct. That's what I stated in my report.
Q. What products are you currently using today to treat prolapse?
A. I perform native tissue repairs, as I always have. I continue to perform transvaginal graft-augmented repairs, but I use biological material to do that, and with permanent sutures using the Capio device. And then I perform sacrocolpopexy using polypropylene mesh.

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Q. Did you use polypropylene-mesh-based kits such as Prolift and Prolift+M up until the time that they were discontinued by Ethicon?
A. I don't remember the exact date, but close to it, yes. I believe my last case was sometime in February of 2012, and I think in July of 2012 was when Prolift and Prolift+M were no longer being offered, so there was a five-month difference.
Q. Why did you stop using these products five months prior to them being discontinued?
A. For the most part, it was based on changing practice patterns.
Q. So your report states that you would still continue to be using these products today if they were available, correct?
A. Correct.
Q. But prior to their discontinuation, you changed your practice pattern such that you quit using them; is that correct?
A. Not that I quit. I started using other procedures. It was a very contentious time after the FDA Public Health Notification. It created a lot of controversy in the media and amongst patients, and so it made the conversations with

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patients very difficult, very time-consuming, very challenging in many ways. I think the emphasis from industry was starting to change towards sacrocolpopexy and other procedures, so as I mentioned earlier in the deposition, that I've continually evolved and adopted new procedures. And the robotic-assisted laparoscopic sacrocolpopexy with Y meshes were really what was starting to come into favor at the time.
Q. So I guess I don't understand. How is it that you would still today be using these products if you have continued to evolve and use newer products? Which is it, Doctor?
A. Well, as I mentioned earlier in the deposition, I might evolve to have my primary procedure or my preferred procedure, but I still like to have a lot of options as a surgeon, and so it's rare that I ever stop or discontinue doing another procedure altogether. So I perform graph-augmented repairs, sacrocolpopexy and native tissue repairs. I've done that for the 15 years I've been in practice. And so I've been very consistent in what I do.
There are patients that I see that are not appropriate for sacrocolpopexy. They've failed

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native tissue. They've failed graft-augmented repair with biologicals, and they would be good candidates for a Prolift or a Prolift+M.
Q. That's a very specific patient profile; isn't that right?
A. That's one of many patients I see in my practice, yes.
Q. But that specific profile you just described, you still consider Prolift would be an appropriate option for that patient, or Prolift+M; is that correct?
A. That's correct.
Q. Would you agree that other surgical techniques are more appropriate for a first-line treatment of prolapse as opposed to Prolift or Prolift+M?
MR. KOOPMANN: Object to form.
A. Primary versus recurrent is just one of the many factors. I look at other factors like the patient's tissue quality, the stage of prolapse, the POPQ store, what their risk-benefit tolerance is. So it's one of many factors that goes into the decision-making of whether or not I'm going to do native tissue on a primary repair or graft-augmented on the primary repair.

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Q. (By Mr. Bentley) And using a graft-augmented repair, is it correct to state that you wouldn't necessarily use a polypropylene-based mesh kit such as Prolift or Prolift+M on every patient that came to you? You might look at other grafts as being more appropriate for that first prolapse surgery; is that correct?

A. Yeah, I've never looked at it that way. I've always offered a variety of procedures based on the indications.

Q. Do you feel that other graft-based repairs are efficacious for some patients that present with prolapse for a first-line treatment surgical option?

A. Yeah, there's certainly a number of patients that I treat with graph augmentation primarily.

Q. Do you feel that that -- strike that.

Do you know if the IFU warns -- strike that.

Do you know if the IFU indicates that Prolift should only be used for select patients, like you've just described, as a first-line surgical treatment for prolapse?

A. The IFU does not -- it's not intended to guide surgeons on which patients they should

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select. That's up to the surgeon and the patient.

Q. And similarly, you don't know if the IFU guides -- strike that.

Similarly, the IFU doesn't guide surgeons as to whether or not Prolift+M and other polypropylene-based prolapse mesh kits is appropriate for first-line surgical treatment of prolapse. The IFU doesn't state that; is that correct?

A. That's correct.

Q. Would you have been critical if Ethicon shared that information with the IFU surgeons?

A. No, I wouldn't have been critical.

Q. Generally, it's advantageous to provide information regarding the patient profile that's appropriate for a surgical option in the IFU. Would you agree that that's helpful and appropriate to put in the IFU?

MR. KOOPMANN: Object to form.

A. No, I'd disagree. I've stated this many times that I don't think that's the role of the IFU.

Q. (By Mr. Bentley) And I appreciate that. That wasn't my question exactly, though.

Do you think it's helpful to have that

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information in the IFU, to have the appropriate patient profile described in the IFU if that information's available?

A. No, it's not helpful. It goes well beyond the scope of the IFU.

Q. Are you aware of any law or regulation that states that the scope is limited such that you can't include patient profile information in the IFU?

A. There's no law, but I believe the standard is to just put what's essential.

Q. Essential to using the product safely, is that correct?

A. That's correct, and helping physicians identify the product.

Q. Are there other patient factors that make Prolift or Prolift+M more appropriate for one patient as opposed to a biological graft?

A. Yeah, there's a long list of factors that we use in the decision-making.

(Exhibit 9 was marked for identification.)

Q. I'm going to hand you what's being marked as Exhibit 9. And this is an e-mail from yourself to Jonathan Fernandez, dated December 19th, 2011. Do you see that?

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A. I do.

Q. Do you recall sending this e-mail to Jonathan Fernandez?

A. I don't.

Q. Up at the top there, that's your e-mail address; isn't that correct?

A. That's correct.

Q. Do you have any reason to doubt that you sent this e-mail in 2011?

A. I don't.

Q. And in the body of the e-mail, you begin, "Jon, All is well with me, although my practice is really changing from mesh kits to Biologicals, ASC and spending time trying to help J&J in a class action vs. Prolift PS"; did I read that correctly?

(Announcement over the intercom.)

Q. (By Mr. Bentley) And you continue, "Ultimately I suspect J&J will pay out millions. I am glad Biosurgery is keeping you busy"; is that correct?

A. That's correct.

Q. Okay. So in December of 2011, it appears that you conveyed to Jonathan Fernandez at Ethicon that you were switching to biologicals; is

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that correct?
A. That's correct.
Q. Okay. And this is approximately eight months before Prolift and Prolift+M are discontinued; isn't that correct?
A. That's correct.
Q. And is it still your opinion that today you would be -- strike that.
Further down in the e-mail, you start out with, "I am starting to look at the AMS products in Coloplast products again as it was our relationship that keep me with Ethicon for the past few years." And you state, "Ethicon is just way too slow to change their prolapse product line"; did I read that correctly?
A. That's correct.
Q. And do you have any understanding as to what you meant by "Ethicon was too slow to change their prolapse product line" that you stated in this e-mail?
A. I do.
Q. And what is that understanding?
A. I had recommended to Ethicon that they spend more time developing some of the biological products similar to AMS and Coloplast and Boston

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Scientific because it seemed to me that that's where the market was going, and also towards sacrocolpopexy. And they did not seem to be developing products for either of those procedures.
Q. And it was your recommendation that they should go into biological products; isn't that correct?
A. I thought it would be helpful, yes.
Q. And just to be clear, biological products are not Prolift or Prolift+M, right?
A. Correct.
Q. Doctor, in your report, you cite to the 2013 Cochrane review; isn't that correct?
A. That's correct.
Q. Are you aware that there's a 2016 Cochrane review?
A. I am.
Q. When did you become aware of that?
A. Probably within the last few months, a few months from when it was published.
Q. Did we discuss earlier as to the whether or not you were aware of any new articles that were relevant to Prolift?
A. We did.
Q. And is there a reason why you didn't

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tell me about the Cochrane 2016 review?
A. I believe my answer was that there may be some new articles. I wasn't absolute on that. I believe I stated that there were some articles that have been recently published that I may or may not be aware of.
Q. And so were you aware of the Cochrane 2016 review when you earlier testified about which articles you had reviewed subsequent to preparing your Prolift and Prolift+M reports?
A. I did, and I believe I've already cited the 2016 Cochrane review a number of times in today's deposition.
Q. Is there a reason that the 2016 Cochrane review did not make it onto your reliance list?
A. This reliance list was prepared primarily for the Delacruz case, which was in the fall of 2015, so the reliance list was not updated, I don't think, after that date, so it probably was not updated on any literature in 2016.
Q. Doctor, do you have your reliance list available in front of you?
A. I do.
Q. I think it was previously entered in the TVT-O deposition. I don't have another copy. I'm

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not sure.
MR. KOOPMANN: It's right there.
Q. (By Mr. Bentley) On the second page of your reliance list after the title page, at the top, it says, "Flynn, Brian." That's you, right?
A. Yes.
Q. Okay. It says, "Materials list, updated February 28, '16"; is that correct?
A. That's correct.
Q. So what you just testified to is this materials list was, in fact, not updated in February of this year like this document purports that it was?
A. I can't say either way. There's a large volume of articles on this reliance list. If it says it was updated, it was updated, but the 2016 review was missed.
Q. Are there any other documents that you know of that were missed?
A. Anything published probably after October 2015 could have been potentially missed.
Q. So it's completely inaccurate that this document says that it was updated in February of this year?
MR. KOOPMANN: Object to form.

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A. No, that's not how I would describe it.
Q. (By Mr. Bentley) Doctor, what date was your expert report signed?
A. It was signed in February of 2016, I believe.
Q. Do you know if the 2016 Cochrane review was published prior to you executing your report in this case?
A. I believe it was.
Q. Doctor, you've previously testified that the Cochrane reviews are important pieces of evidence in this case; isn't that true?
A. That's true.
Q. So can you explain to me why you don't think it was important to include the 2016 Cochrane review regarding prolapse in your report?
MR. KOOPMANN: Object to form; misstates his testimony.
A. I do think it's an important document.
Q. (By Mr. Bentley) And potentially the 2016 Cochrane review, which you think is an important document, could change your opinions in this case; isn't that correct?
A. I don't think it's going to change my opinions very much, no.

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Q. Could it have changed your opinions in this case?
A. Could it have? There's always a possibility, but I think it's unlikely that it would have.
Q. Would you have liked an opportunity to adequately review the 2016 Cochrane review before reaching your opinions in this case?
MR. KOOPMANN: Object to form.
A. Not necessarily. I feel that I had a wealth of information on a product that was very well-studied.
Q. (By Mr. Bentley) Do you know if the 2016 Cochrane review included a number of studies that weren't included in the 2013 review?
A. I don't know the answer to that.
Q. Do you know if the 2016 Cochrane review included nine studies that weren't included in your reliance materials in preparation for this report?
A. I wasn't aware of that.
Q. Do you know if you reviewed the Dahlgren study? I'll represent to you it's not on your reliance list, but as you've testified, we can't rely upon your reliance list, so my question to you is, do you know, or are you familiar with the

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Dahlgren study?
MR. KOOPMANN: Object to form.
A. I don't believe I'm familiar with it.
Q. (By Mr. Bentley) Are you familiar with the Delroy study?
A. Which study?
Q. The Delroy study.
MR. KOOPMANN: How do you spell that?
MR. BENTLEY: D-e-l-r-o-y.
A. I don't believe so.
Q. (By Mr. Bentley) Okay. Are you familiar with the Lamblin study, L-a-m-b-l-i-n?
A. I would have to look at the article to be certain.
Q. So you're not familiar with it as you sit here today?
A. Correct.
Q. Are you familiar with the Qatawneh, Q-a-t-a-w-n-e-h, study?
A. No.
Q. Are you familiar with the Robert study published in 2014?
A. No.
Q. Are you familiar with the Rudnicki study published in 2014? R-u-d-n-i-c-k-i.

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A. No.
Q. Are you familiar with the Sung 2012 study? S-u-n-g.
A. I'd have to go back and look at the reliance list.
Q. I'll represent to you that that study's not on your reliance list. As you sit here today, are you familiar with it?
A. Probably not familiar with it, then.
Q. Do you think you need to add that study to your reliance list?
A. I don't know one way or another.
Q. Are you familiar with the 2014 Tamanini, T-a-m-a-n-i-n-i, study?
A. As I stated earlier, there's a number of studies out that I can't possibly cite every single study in this report or on this reliance list.
Q. So is it your testimony that you haven't reviewed all the relevant literature related to Prolift and Prolift+M?
MR. KOOPMANN: Object to form.
A. That's not my testimony.
Q. (By Mr. Bentley) Do you know if you've reviewed all the relevant Prolift and Prolift+M expert -- strike that.

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Do you know if you've reviewed all the relevant Prolift and Prolift+M literature in preparing your report and your opinions in this case?

A. I reviewed enough information to stand behind my opinions in this report.

Q. And do you know if you reviewed or are you familiar with the Turgal 2013 study? T-u-r-g-a-l.

A. I'm not familiar with that study.

Q. If any of those studies had reached conclusions that were contrary to your opinions in this case that you've presented in this report, would that have affected your opinions here?

A. I don't think so.

Q. Is there anything out there in the medical literature that you haven't reviewed that could possibly change your opinions here?

A. There's always possibilities, but I think it's unlikely.

Q. And you just testified that those nine studies that you haven't reviewed, that you don't think any of those would have affected your opinions here; is that correct?

A. I think my opinion was that it's

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unlikely that it would.

Q. And if the 2016 Cochrane review, which you've testified that you've reviewed, if they identified these new studies that they thought were important to list -- if the Cochrane review thought these studies were important to list out as being new additions to their studies since 2013, you don't agree that those studies were important in reaching your opinion here; is that fair?

A. That's fair.

Q. Are you aware that the 2016 Cochrane review that you testified that you reviewed has reached conclusions that the risk of mesh might not be outweighed by the benefits associated with recurrence in using Prolift or Prolift+M mesh kits?

MR. KOOPMANN: Object to form.

A. I'm aware of that, yes.

Q. (By Mr. Bentley) And that doesn't affect your opinion here?

A. I think I've stated my opinions very well, so I don't have any other opinions in regards to that.

Q. So it doesn't affect your opinion?

A. No.

Q. Okay. And are you aware that the

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Cochrane 2016 review concludes that limited evidence suggests that absorbable mesh may reduce rates of recurrent prolapse on examination compared to native tissue repair, but there was insufficient evidence on absorbable mesh for us to draw any conclusions for other outcomes? Are you aware of that?

A. That the outcomes of absorbable mesh?

Q. That there's limited evidence regarding other outcomes associated with absorbable mesh.

A. I never used absorbable mesh, and I don't really talk about it in my report.

Q. Are you aware that Prolift+M has an absorbable mesh component?

A. It has a component, but it's -- you know, I thought you were referring to purely absorbable meshes like Vicryl mesh or Dexon mesh.

Q. So do you disagree with the conclusions in the 2016 Cochrane review?

MR. KOOPMANN: Object to the form.

A. I used the earlier Cochrane review to formulate my opinions in this report.

Q. (By Mr. Bentley) And the additional literature that we've discussed that you haven't reviewed doesn't affect or alter your opinions; is

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that correct?

A. It does not.

Q. And as you sit here today, do you have any critiques or criticisms of the 2016 Cochrane systematic review of the literature regarding transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse? Do you have any criticisms or critiques of the systematic review published in 2016?

A. No.

Q. And you've previously testified that this is, in fact, one of the highest levels of evidence available; is that correct?

A. That's correct.

MR. BENTLEY: I have no further questions right now, Doctor. Thank you.

EXAMINATION

BY MR. KOOPMANN:

Q. Dr. Flynn, if the 2016 Cochrane review that plaintiffs' counsel's been asking you about says that awareness of prolapse at one to three years was less likely after mesh repair, is that consistent with the opinions set forth in your report?

MR. BENTLEY: Objection; leading.

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A. I believe so. Yes, it is.
Q. (By Mr. Koopmann) And if the 2016 Cochrane review that plaintiffs' counsel asked you questions about says that rates of repeat surgery for prolapse were lower in the mesh group, would that be consistent with your opinions regarding the safety and efficacy of the Prolift and Prolift+M devices?
MR. BENTLEY: Objection; form.
A. Yes, it would.
Q. (By Mr. Koopmann) That statement is saying that mesh repairs help patients avoid the risks of reoperation that plaintiffs' counsel asked you about earlier; isn't that right?
MR. BENTLEY: Objection; misstates, form, leading.
A. That is correct.
Q. (By Mr. Koopmann) And if the 2016 Cochrane review says that recurrent prolapse on examination was less likely after mesh repair, would that be consistent with your opinions regarding the Prolift and Prolift+M's safety and efficacy?
MR. BENTLEY: Objection; form.
A. Yes, it would.

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Q. (By Mr. Koopmann) And if the 2016 Cochrane review by Dr. Maher and colleagues says that there was no evidence of a difference between the native tissue repair group and the mesh repair group and the rates of de novo dyspareunia, would that be consistent with your opinions regarding the safety and efficacy of the Prolift and Prolift+M products?
MR. BENTLEY: Objection.
A. Yes, that would be.
Q. (By Mr. Koopmann) The question -- or plaintiffs' counsel asked you questions about this e-mail that you sent to Jonathan Fernandez. Do you recall these questions?
A. I do.
Q. Did you suggest that Ethicon pursue blockage products or abdominal sacrocolpopexy products because you thought those were safer than transvaginal mesh products?
MR. BENTLEY: Objection.
A. No.
Q. (By Mr. Koopmann) The Velemir study that plaintiffs' counsel asked you about that was marked as Exhibit 8, that was published in the Ultrasound in Obstetrics and Gynecology journal?

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A. Correct.
Q. So it was published for the whole world to see?
A. I think very few people would see that. It's not a widely published or distributed journal.
Q. But any doctor interested in learning about transvaginal mesh repair of anterior and posterior vaginal wall prolapse could find that article?
A. Yes --
MR. BENTLEY: Objection.
A. -- they could.
Q. (By Mr. Koopmann) Your article that you co-authored with Dr. Terlecki written in the AUA update series in 2010, were you paid to write that article?
A. A very small fee, yes.
Q. Do you recall what it was?
A. $250. And I split that with Dr. Terlecki.
Q. $250 per hour?
A. No, total.
Q. And how long would you say you spent writing this article with Dr. Terlecki?
A. Well, the article's about 5,000 words,

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and we probably spent between 40 and 50 hours writing the article.
Q. And did anyone from Ethicon ever talk to you after they saw the article and ask you why you wrote this article?
MR. BENTLEY: Objection.
A. Nobody talked to me before or after the article.
Q. (By Mr. Koopmann) Did Ethicon continue to consult with you after the publication of this article?
A. Yes. As I stated earlier in the deposition, I presented an exhibit of my consulting relationship going through 2011. I did the TVT-Abbrevo video in 2011 after that article. I was part of the TVT Exact launch, so I still continued to consult after that publication.
Q. And did you keep all of the $250 that you were paid for writing this article we marked as Exhibit 7?
A. No, I shared half of it with my fellow, Ryan Terlecki.
Q. So you got $125, he got $125?
A. That's correct.
Q. And so if you took 40 hours to write the

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article at -- for $125, that'd be about $3 per hour you got for writing this article; is that about right?

MR. BENTLEY: Objection.

A. That's right. We don't write these articles for monetary gain.

Q. (By Mr. Koopmann) Why did you write this article?

A. Well, first off, I was asked to write it by the American Urologic Association. The American Urologic Association was getting a number of phone calls from its members about how it should interpret and respond to the FDA Public Health Notification of 2008. They asked us to provide useful information. The AUA Update series is a CME series, so that's a CME document, that's why there's questions and answers at the end of the document. That's why there's parts bolded so people who read the document can read all of it or some of it. Most of the questions in that paper come from the bolded area, so we're asked to intentionally bold a certain percentage of the paper. So that was intended as an instrument to educate my colleagues, residents, fellows, physicians in practice about polypropylene mesh,

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about incontinence, prolapse, and the FDA Public Health Notification.

Q. (By Mr. Koopmann) And plaintiffs' counsel asked you some questions about a sentence that says, "Patient factors that may lead to an increased risk for extrusion include age, estrogen status, prior radiation, active vaginal infection, smoking, obesity, immunosuppression, diabetes, and concomitant hysterectomy"; do you remember that?

A. I do.

Q. And the next sentence you wrote says, "Many patients with adverse implantation features also have weak connective tissue and are at high risk for failure if a graft is not used," is that right?

A. That's correct.

Q. Do you still stand by that opinion today as well?

A. I do.

Q. In the summary of this article that's been marked as Exhibit 7, you say in bold print, "Surgeons with diverse backgrounds have been able to achieve excellent results in primary and secondary repairs for SUI with polypropylene mesh. Similarly, mesh reinforcement reduces the incidence

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of delayed failures after POP surgery while transvaginal placement minimizes postoperative morbidity." Do you still stand by those opinions?

MR. BENTLEY: Objection.

A. I do.

Q. (By Mr. Koopmann) Or that statement, I should say.

MR. BENTLEY: Objection.

A. I do, very much so.

Q. (By Mr. Koopmann) And you went on to say, "Superior cure rates with mesh are contrasted with the introduction of unique and sometimes serious graft complications. Therefore, reinforced pelvic floor repairs should only be performed in well-selected patients after they provide informed consent"; is that right?

MR. BENTLEY: Objection; leading.

Q. (By Mr. Koopmann) That's what you said?

A. That's what I said.

Q. Do you feel like you were objective in writing this report?

MR. BENTLEY: Objection.

Q. (By Mr. Koopmann) Or this article?

A. Absolutely. I disclosed my conflicts of interest on the front page. The article was

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reviewed by three reviewers. I responded to the reviews. And I do feel that this article was an objective piece of information.

Q. And do you think it is the case that native tissue repairs for pelvic organ prolapse should only be performed in well-selected patients after they provide informed consent?

MR. BENTLEY: Objection; form, leading.

A. Yes. Any time you perform any kind of surgery, you want to make sure you properly select your patient regardless what the surgery is and what procedure you select. You want to be very careful in that procedure selection.

Q. (By Mr. Koopmann) The article marked as Exhibit 6 by Dr. -- lead author, or first listed author, Beri Ridgeway, that's titled "Early experience with mesh excision for adverse outcomes after transvaginal mesh placement using prolapse kits," is that right?

A. That's correct.

Q. That's from December 2008?

A. Yes.

Q. So that's eight years old at this point, almost?

MR. BENTLEY: Objection.

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A. Correct.
Q. (By Mr. Koopmann) You were asked some questions about RCT by Dr. Cheryl Iglesia, Andrew Sokol and others that was marked as Exhibit 4. Do you recall those questions?
A. I do.
Q. In preparing your opinions regarding the Prolift and Prolift+M devices, did you also review and rely on RCT by Andrew Sokol and Cheryl Iglesia and others on their one-year outcomes following native tissue repair versus mesh repair?
MR. BENTLEY: Objection; form, leading, compound.
A. Yeah, that's cited in my report, the one one-year objective and functional outcomes of randomized clinical trial of vaginal mesh for prolapse.
Q. (By Mr. Koopmann) And they studied 32 women who had a mesh repair and 33 women who had a traditional repair; is that right?
MR. BENTLEY: Same objection.
A. Yes, that's correct.
Q. (By Mr. Koopmann) And they found that the quality of life improved and did not differ between the two groups, 96.2 percent in the mesh

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group and 90.9 percent in the no-mesh group; is that right?
MR. BENTLEY: Same objection.
A. That's correct.
Q. (By Mr. Koopmann) Those are the percentages of the subjects that reported a cure of bulge symptoms; is that right?
MR. BENTLEY: Same objection.
A. Yes, that's correct.
Q. (By Mr. Koopmann) They also reported that postoperative subjective quality-of-life measurements showed statistically significant improvements from baseline for both the mesh and no-mesh groups for almost all quality-of-life measurements and did not differ between the two groups one year after the procedure; is that right?
MR. BENTLEY: Objection.
A. Yes, that's right.
Q. (By Mr. Koopmann) And is that consistent with your opinions regarding the safety and efficacy of the Prolift device?
MR. BENTLEY: Objection.
A. It is.
Q. (By Mr. Koopmann) The authors also noted based on their one-year follow-up in this RCT

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that sexual function based on the prolapse and incontinence sexual questionnaire scores was similar before the procedure between mesh and no-mesh groups, and improved significantly in both groups 12 months after the procedure; is that right?
MR. BENTLEY: Objection.
A. Yes, that's right.
Q. (By Mr. Koopmann) And they found that there was no significant difference between the groups with regards to sexual function 12 months after the procedure; is that right?
A. Yes, that's right.
Q. They also noted that in the group of patients who did not have mesh, 15 percent had apical Gor-Tex suture exposures; is that right?
MR. BENTLEY: Objection.
A. That's correct.
Q. (By Mr. Koopmann) And two women complained of vaginal discharge and required suture removal in the office at six and nine months after the procedure?
MR. BENTLEY: Objection.
A. Correct.
Q. (By Mr. Koopmann) They found no

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statistically significant differences between the mesh and no-mesh groups with respect to long-term complications, did they?
MR. BENTLEY: Objection.
A. That's correct.
Q. (By Mr. Koopmann) And, in fact, even based on their three-month outcomes that were reported on Exhibit 4, they noted that subjective quality-of-life measurements did not differ between the two groups at baseline or three months postoperatively; is that right?
MR. BENTLEY: Objection.
A. That's right.
Q. (By Mr. Koopmann) The "Adverse Reactions" section of the Prolift IFU indicates that potential adverse reactions are those typically associated with surgically implantable materials, including infection potentiation, inflammation, adhesion formation, fistula formation, erosion, extrusion, and scarring that results in implant contraction; is that correct?
MR. BENTLEY: Objection; form, foundation, leading.
A. That's correct.
Q. (By Mr. Koopmann) And do you think that

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pelvic floor surgeons would know, based on that sentence that I just read, that that pain is a possibility with the implantation of a Prolift device?

MR. BENTLEY: Objection; form, leading, foundation, speculation.

A. Yes, absolutely.

Q. (By Mr. Koopmann) And is it fundamental medical and surgical knowledge that pain can result after any surgery, whether it's a mesh surgery or nonmesh surgery?

MR. BENTLEY: Objection.

A. Any kind of surgery, yes.

Q. (By Mr. Koopmann) And is it fundamental medical knowledge that if pain results after a surgery, it could be mild or moderate or severe?

MR. BENTLEY: Same objection.

A. That's correct.

Q. (By Mr. Koopmann) And is it also fundamental medical knowledge that if pain results after a surgery, that the pain could be temporary or permanent?

MR. BENTLEY: Objection.

A. That's correct.

Q. (By Mr. Koopmann) Permanent pain can

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result after a native tissue repair, can it?

MR. BENTLEY: Objection.

A. Correct.

Q. (By Mr. Koopmann) Can dyspareunia result after a native tissue repair?

A. That's correct.

Q. Can an infection occur in a native tissue repair?

MR. BENTLEY: Objection.

A. Correct.

Q. (By Mr. Koopmann) The IFU also notes that punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during Gynecare Prolift guide passage and may require surgical repair; is that right?

A. Yes, that's right.

Q. And does that sentence also tell you and other surgeons that pain could result from implantation of the Prolift device?

MR. BENTLEY: Objection.

A. That's correct.

Q. (By Mr. Koopmann) Did you discuss the Prolift Surgeon's Resource Monograph at professional education events?

A. Yes, we did.

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MR. KOOPMANN: Mark this as whatever the next exhibit is, please.

(Exhibit 10 was marked for identification.)

Q. (By Mr. Koopmann) Handing you what's been marked as Deposition Exhibit 10, do you recognize this document?

A. I do.

Q. What is it?

A. This is a Gynecare Prolift Surgeon's Resource Monograph. This is a document that was published by high-volume Prolift users to help physicians in practice understand some of the technical pearls that some of the surgeons that had done a significant amount of Prolift procedures to share their experience with the device.

Q. And this was provided by Ethicon?

A. It was.

Q. And was it made available to pelvic floor surgeons?

MR. BENTLEY: Objection.

A. Yes, it was. That was the intent of the report.

Q. (By Mr. Koopmann) Is there anything like this Surgeon's Resource Monograph that exists for native tissue repairs?

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MR. BENTLEY: Objection.

A. No.

Q. (By Mr. Koopmann) Does this Surgeon's Resource Monograph discuss various complications possible with the Prolift surgery?

MR. BENTLEY: Objection.

A. It does. And I've used one of the tables from the monograph in my report.

Q. (By Mr. Koopmann) Like the table at page 10?

A. That's correct.

Q. And that provides a citation to eight studies in the top table setting forth how many patients were involved in the studies, what the follow-up period was, what the exposure rates were, what the success rates were, and some of the other complications that occurred in connection with the use of the Prolift devices, correct?

MR. BENTLEY: Objection.

A. That's correct. It has a total of 549 patients, six-month follow-up, exposure rate between 2.6 and 6.2 percent, 81 to 100 percent success, and then injuries, including rectal injury, 1.7; bleeding, 1.3; retention, 6.7; cystotomy, 1.7.

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Q. (By Mr. Koopmann) Some of the exposure rates reported are -- you know, the Rivera study shows an 11.7 exposure rate?
MR. BENTLEY: Objection.
A. That's correct.
Q. (By Mr. Koopmann) The page opposite that, there's a discussion of dyspareunia and vaginal pain that can occur; is that correct?
A. That's correct.
Q. Is this a document that you found helpful in your practice?
MR. BENTLEY: Objection.
A. It is.
Q. (By Mr. Koopmann) Have you seen a decrease in efficacy in the patients that you've treated for pelvic organ prolapse, let's say for cystoceles, since you stopped using Prolift and Prolift+M?
MR. BENTLEY: Objection.
A. Can you repeat the question?
Q. (By Mr. Koopmann) Have you seen a decrease in efficacy in the patients that you've treated for pelvic organ prolapse, let's say for cystoceles, since you stopped using Prolift and Prolift+M?

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MR. BENTLEY: Same objection.
A. Yes, I have.
Q. (By Mr. Koopmann) And is that one of the reasons that you would still like to have the ability to use Prolift or Prolift+M in certain patients?
MR. BENTLEY: Objection; form, leading.
A. Correct.
Q. (By Mr. Koopmann) And is the same true for rectocele repairs?
MR. BENTLEY: Objection.
A. Correct.
Q. (By Mr. Koopmann) One of the studies you cited in your report is the 2013 Cochrane review by Dr. Maher and others; is that correct?
A. That's correct.
Q. And one of the things that study noted -- well, first of all, that's something you relied on in forming your opinions regarding the Prolift and Prolift+M devices?
A. Yes.
Q. And in that study, the authors noted that standard anterior repair was associated with more anterior compartment prolapse on examination than for any polypropylene permanent mesh repair;

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is that right?
MR. BENTLEY: Objection; form, foundation, leading.
A. Yes, that's correct.
Q. (By Mr. Koopmann) And they also noted that awareness of prolapse was also higher after the anterior repair as compared to the polypropylene mesh repair; is that right?
MR. BENTLEY: Same objection.
A. Yes, that's correct.
Q. (By Mr. Koopmann) They also noted, however, the reoperation rate for prolapse was similar at 14 out of 459, 3 percent, after the native tissue repair compared to 6 out of 470, 1.3 percent, after the anterior polypropylene mesh repair, and no differences in quality-of-life data or de novo dyspareunia were identified; is that right?
MR. BENTLEY: Same objection.
A. That's correct.
Q. (By Mr. Koopmann) And the mesh erosion rate reported there was 11.4 percent?
MR. BENTLEY: Same objection.
A. Yes.
Q. (By Mr. Koopmann) Which was 64 out of

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563 patients?
MR. BENTLEY: Same objection.
A. That's correct.
Q. (By Mr. Koopmann) And then surgical interventions were performed in 6.8 percent of the patients?
MR. BENTLEY: Objection.
A. That's correct.
Q. (By Mr. Koopmann) You relied on an article by Dr. Svabik, and others, that's in RCT regarding Prolift use; is that right?
A. Yes, that's correct.
Q. And that study looked at 142 patients who were post hysterectomy and underwent surgery for prolapse. Seventy-two of them were diagnosed with an avulsion injury and were offered participation in the study, and the 70 patients -- and 70 patients were randomized in two groups, 36 in the Prolift group and 34 in the sacrospinous fixation group; is that right?
MR. BENTLEY: Objection; form, foundation, leading.
A. That's correct.
Q. (By Mr. Koopmann) And on clinical examination at one year follow-up, they observed

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one case of anatomical failure in the Prolift group and 22 cases of anatomical failure in the sacrospinous fixation group; is that right?
MR. BENTLEY: Same objection.
A. That's correct.
Q. (By Mr. Koopmann) So the anatomical failure rate in the Prolift group was 3 percent, and the anatomical failure rate in the native tissue repair group was 64 percent?
A. That's correct.
MR. BENTLEY: Objection.
Q. (By Mr. Koopmann) And that difference was statistically significant?
MR. BENTLEY: Objection.
A. Yes, it was.
Q. (By Mr. Koopmann) Is this an article that you relied on in forming your opinions regarding the safety and efficacy of the Prolift device?
A. Yes.
Q. They also reported that sexual activity was not influenced by the type of surgery; is that right?
MR. BENTLEY: Objection.
A. That's correct.

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Q. (By Mr. Koopmann) You also relied on an article by -- an RCT by lead author with the last name da Silveira; is that correct?
A. That's correct.
Q. And in that study, they looked at 184 women with POPQ stage 3 or 4 prolapse who were randomly assigned to undergo surgical treatment using either native tissue repair or synthetic mesh repair with Prolift; is that right?
MR. BENTLEY: Objection.
A. Yes, that's correct.
Q. (By Mr. Koopmann) And at one year, follow-up anatomical cure rates were better in the mesh group in the anterior compartment; is that correct?
MR. BENTLEY: Objection.
A. Yes, that's correct.
Q. (By Mr. Koopmann) And also significant improvement in patient quality of life scores at one year follow-up were observed in each group; is that right?
MR. BENTLEY: Objection.
A. Yes, that's right.
Q. (By Mr. Koopmann) And between group comparisons of changes in the patient

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quality-of-life scores revealed greater improvement in the mesh group; is that right?
MR. BENTLEY: Objection.
A. Yes, that's right.
Q. (By Mr. Koopmann) They also noted on page -- well, it's the second-to-last page, I don't know if it's numbered, "On analysis of this study, one must take into account that, although the tested mesh product, Prolift, has been withdrawn from the world market, its material has the optimal properties of a mesh for pelvic floor repairs"; is that right?
MR. BENTLEY: Objection.
A. That's right.
Q. (By Mr. Koopmann) They included a table, numbered Table 6, that set forth complications and complaints at one-year follow-up, and it indicated that 6.2 percent of the native tissue patients had dyspareunia at one-year follow-up, and 3.4 percent of the patients had dyspareunia in the mesh group; is that right?
MR. BENTLEY: Objection.
A. Yes, that's right.
Q. (By Mr. Koopmann) And pain was experienced by 8.6 percent of the women in the

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native tissue group at one-year follow-up, but only 2.3 percent in the mesh group; is that also right?
MR. BENTLEY: Objection.
A. Yes, that's right.
Q. (By Mr. Koopmann) Is it fair to say that there are randomized control trials regarding the Prolift device that report both very positive things about the Prolift device and not-so-positive things about the Prolift device?
MR. BENTLEY: Objection; form.
A. Yes, that's correct.
MR. BENTLEY: Compound, leading, speculation.
Q. (By Mr. Koopmann) And you took all of those randomized control trials into account, the ones cited in your report, in forming your opinions in this case; is that correct?
A. Yes, I did.
MR. BENTLEY: Objection.
Q. (By Mr. Koopmann) And you discussed in your report some randomized control trials that you're relying on in support of your opinions regarding the Prolift and Prolift+M devices by authors such as Halaska, Whithagen, Carey and Altman; is that right?

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A. Yes.
Q. And you hold the opinions set forth in your Prolift and Prolift+M reports to a reasonable degree of medical certainty?
A. I do.
Q. Why is it that you didn't ask to see internal corporate depositions of Ethicon personnel?
A. Because I didn't think it was relevant to me in formulating my opinions in preparing this report.
Q. Did you rely on higher-level evidence than internal corporate depositions?
A. I did. Depositions are not levels of evidence. They're a person's response to questions that they were asked. We relied on randomized control trials, meta-analyses and systematic reviews primarily in preparation of this report.
Q. Is it true that sometimes two authors setting out to review a body of literature, let's say, for purposes of a systematic review of literature end up reviewing somewhat different bodies of literature for whatever reason?
MR. BENTLEY: Objection; form, date, speculation, foundation.

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A. Absolutely. There can be biases even in systematic reviews. And so just like I've been questioned about why I selected which articles to review here, the reviewers of a systematic review have the ability to pick and choose which articles they want to include in their systematic review.
Q. (By Mr. Koopmann) You talked earlier about your case log, and I think you indicated essentially that when you have patients return to you after surgery, you ask them how they're doing, and various questions, including whether they're happy that they had their procedure; is that accurate?
A. That's accurate.
Q. When you had patients return to you after Prolift surgeries, what did they generally report to you regarding whether they were happy that they had the procedure?
MR. BENTLEY: Object.
A. The overwhelming majority of them were happy that they had the procedure done. Many of these patients had had prolapse that was very bothersome to them. Many of them were recurrent patients and had been unable to have their prolapse resolved with other procedures such as native

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tissue repair, sacrocolpopexy and graph-augmented repairs with biologicals.
Q. (By Mr. Koopmann) Even if you didn't do a systematic review of your case log, do you, nonetheless, have a good understanding of the complication rates that you saw in your practice using the Prolift and Prolift+M devices?
MR. BENTLEY: Objection; form, foundation, speculation.
A. Yes, I am aware.
Q. (By Mr. Koopmann) And are those complication rates the same ones that you would report to patients who asked you about complications when considering possibly having a Prolift or Prolift+M surgery?
MR. BENTLEY: Same objection.
A. Yes. When most surgeons are discussing risks and benefits of a procedure with their patients, they're using both their own personal experience and then what the medical literature shows.
Q. (By Mr. Koopmann) Was the literature search that you performed for purposes of the preparation of your Prolift and Prolift+M reports -- was it the same basic methodology that

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you use in doing literature searches for purposes of your clinical practice?
MR. BENTLEY: Objection.
A. Yes, clinical practice and publications.
Q. (By Mr. Koopmann) Is there any reliable literature that you're aware of that suggests that Gynemesh PS or Ultrapro mesh is toxic or carcinogenic?
MR. BENTLEY: Objection.
A. I don't believe that the reports that suggest that are valid, so the answer is no.
Q. (By Mr. Koopmann) Erosion rates for Prolift or Prolift+M are set forth in the published medical literature; is that correct?
MR. BENTLEY: Objection.
A. Correct. It's widely stated in the medical literature, in this report and in various RCTs and systematic reviews.
MR. BENTLEY: Strike after "literature."
Q. (By Mr. Koopmann) Cochrane reviews, like the 2013 Maher Cochrane review that you reviewed and relied on in forming your opinions, they study and take into account and analyze all literature on a certain subject regardless of whether it reports excellent or poor outcomes using

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a certain surgical intervention; is that true?
MR. BENTLEY: Objection to form; foundation, leading, compound.
A. Correct. The goal of a systematic review is to select articles that meet a certain criteria for inclusion, and whether those report positive or negative outcome shouldn't influence the selection of those articles.
Q. (By Mr. Koopmann) Can adding information to an IFU potentially be unhelpful?
MR. BENTLEY: Objection; form, foundation.
A. Yes.
Q. (By Mr. Koopmann) How so?
A. Well, if there's too much information in the IFU, just like that package insert you get at your pharmacy, you're less likely to read it. So there's a danger of information overload, especially in today's era. So I think that that information may not be looked at if there's too much information there, or surgeons might not read it in its entirety.
MR. BENTLEY: Move to strike, speculation.
Q. (By Mr. Koopmann) If too much information is included in an IFU, do you think it could potentially obscure other important

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information?
MR. BENTLEY: Objection; form, foundation, speculation.
A. Yes, I think the important information may be overlooked if the person reading the IFU is not reading every word of the IFU.
Q. (By Mr. Koopmann) Do you need information included in an IFU that you learned in medical school and residency?
A. No.
Q. Do you need all surgical complications to be included in an IFU?
MR. KOOPMANN: Objection.
A. I do not, nor is that even possible or relevant.
Q. (By Mr. Koopmann) Can vaginal shortening occur after a native tissue repair?
MR. BENTLEY: Objection.
A. Yes.
Q. (By Mr. Koopmann) Can dyspareunia occur after a native tissue repair?
A. Yes.
MR. BENTLEY: Objection; asked and answered, form, foundation.
Q. (By Mr. Koopmann) Can infection occur

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after a native tissue repair?
MR. BENTLEY: Same objection.
A. Yes, it can.
Q. (By Mr. Koopmann) Pull up your Prolift report. You've got it in front of you.
Plaintiffs' counsel asked you earlier why you didn't reference or discuss infection in your Prolift report. Do you remember that?
MR. BENTLEY: Objection; misstates.
A. I do.
Q. (By Mr. Koopmann) Turn to page 14, please. The bottom paragraph there, you talk about how native tissue repairs can cause infection; is that right?
A. Correct.
Q. And if you'll turn to -- I'm sorry. Okay. You're on 14?
A. Yes.
Q. Okay. That question was actually about page 10.
A. Okay.
Q. Did you talk about the risk of infection with native tissue repairs?
A. Yes. It says, "In summary, native tissue repairs can cause numerous complications,

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such as bleeding, infection, dyspareunia, pain, injury to surrounding organs, including bladder, bowel, rectum, or ureter. More damage or entrapment can occur leading to chronic pain, chronic groin or buttock pain."
Q. Now turn to page 14, please. The second-to-last full paragraph, you indicate the pore size of Gynemesh PS is about 2.5 millimeters, or 2,500 microns, which easily accommodates the cells and small blood vessels needed to access the pores, promote tissue integration and reduce the risk of infection; is that correct?
A. That's correct.
Q. So you're noting there that there is a risk of infection with the Gynemesh PS; is that true?
A. That's true.
Q. And turn to page 20, please. You note in the last sentence of the first paragraph that the DeLande Sheere study reported surgery due to mesh infection occurred in .2 percent of the patients in that study; is that right?
A. That's right.
Q. Can pelvic pain occur after native tissue repair?

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A. Yes.
Q. Is it a good idea for a doctor to try to mitigate factors that could cause a wound complication before doing a native tissue surgery?
A. Yes.
Q. So for instance, if a patient was a smoker and came to you and the two of you agreed that she was going to have a native tissue surgery for her pelvic organ prolapse, it would be a good idea to counsel her to stop smoking for that reason, and others?
MR. BENTLEY: Objection; form, leading.
A. For that reason, and others. I talk about smoking cessation with all my patients regardless of the surgeries.
Q. (By Mr. Koopmann) Is it a surgeon's responsibility to make sure he or she is familiar with the steps for implanting a medical device?
MR. BENTLEY: Objection; form, foundation.
A. Yes.
Q. (By Mr. Koopmann) Can contracted scar tissue occur in a native tissue repair?
MR. BENTLEY: Objection; form, foundation.
A. Yes.
Q. (By Mr. Koopmann) If that occurs in a

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native tissue repair, can it cause pain?
MR. BENTLEY: Objection.
A. Yes.
Q. (By Mr. Koopmann) Can excessive tension from sutures used in a native tissue repair cause pain?
MR. BENTLEY: Objection.
A. Yes.
Q. (By Mr. Koopmann) Can nerve injury result from a native tissue repair?
A. Yes.
Q. And that could cause pain?
A. Yes.
Q. You performed some professional education for Ethicon regarding Prolift; is that right?
A. Yes, that's correct.
Q. Did you also do it for Prolift+M?
A. Yes.
Q. Why did you do that?
A. Because I enjoy teaching. It's always been a big part of my practice, teaching medical students, residents and physicians in practice. I think we have an obligation to help physicians in practice learn how to do new procedures. I felt

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that I had expertise that I could offer others. Especially as a urologist, there's less urologists that are trained and familiar with prolapse repairs. And I tend to network well with urologists. And I had a number of people request that I help educate them on the product.
Q. Did you teach your residents or fellows at the University of Colorado how to implant Prolift devices?
A. I did.
Q. Did you teach your residents or fellows at the University of Colorado how to implant Prolift+M devices?
A. Yes, I did.
Q. Did Ethicon pay you to do that teaching?
A. No, they did not.
Q. Why did you teach your residents and fellows at the University of Colorado to implant Prolift and Prolift+M devices, among other prolapse procedures?
A. Because it's an important part of their education and training. Residents and fellows, when they graduate, in their own practice will see women with incontinence and prolapse. I want them to feel well-prepared in performing the

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contemporary procedures.
Q. Do you know whether the TVM group evaluated a larger pore lightweight mesh in the development of what became Prolift?
MR. BENTLEY: Objection.
Q. (By Mr. Koopmann) Other than Gynemesh PS?
MR. BENTLEY: Objection.
A. I believe the TVM group looked at multiple meshes before they evolved to what they felt was the ideal mesh.
Q. (By Mr. Koopmann) And they felt Gynemesh PS was the ideal mesh?
MR. BENTLEY: Objection.
A. That's correct.
Q. (By Mr. Koopmann) Do you think that the complications reported in the IFUs for the Prolift and Prolift+M devices are consistent with the complications that you saw in your clinical practice using those devices?
MR. BENTLEY: Objection.
A. Yes, that is consistent.
Q. (By Mr. Koopmann) Did you base your opinions today regarding the adequacy of the warnings in the Prolift, the Prolift+M IFUs on all

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of your experience, education, training and review of the literature?
MR. BENTLEY: Objection.
A. That is correct.
Q. (By Mr. Koopmann) Is Gynemesh PS the most studied mesh for use in prolapse surgery?
MR. BENTLEY: Objection; form, foundation, speculation.
A. Yes, it is.
MR. KOOPMANN: Those are all the questions I have for you, Dr. Flynn.
EXAMINATION
BY MR. BENTLEY:
Q. Dr. Flynn, just a couple follow-ups.
In the 2016 Cochrane review that you've reviewed prior to today, the authors conclude that transvaginal permanent mesh kits such as Prolift are associated with higher rates of reoperation for prolapse, stress urinary incontinence or mesh exposure, and higher rates of bladder injury at surgery and de novo urinary incontinence. Do you agree with that conclusion?
A. I would have to separate all those statements. There's a lot there to agree or disagree with.

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Q. Okay. Do you agree that permanent mesh kits for prolapse like Prolift are associated with higher rates of reoperation for prolapse?
A. No, I don't agree with that.
Q. And in your report, you haven't given us any reason to your methodology in reaching a disagreement with the systematic review of Cochrane that was published in 2016; isn't that correct?
A. That's not correct.
Q. I'm sorry. Where in your report do you give us any type of analysis as to why you disagree with this 2016 Cochrane review's conclusions?
A. Because I think I cite other Cochrane reviews from Maher as well as other systematic reviews suggesting that just the opposite, that the incidence of reoperation is lower with graft-augmented repair such as Prolift when compared to native tissue repair.
MR. KOOPMANN: Object to the form of that last question.
Q. (By Mr. Bentley) Do you have any knowledge or understanding as to what this 2016 Cochrane review is the largest study ever performed to collect and review -- strike that.
Do you have any knowledge or understanding

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that this is the most recent and largest systematic review of all the available prolapse and Prolift-related literature?
A. I don't have knowledge if that's the largest. As meta-analyses are published, the more recent ones tend to have more data as they collect more data, as more studies are published, so that's a general observation I would have.
Q. And this is more recent than the 2013 Cochrane review that you cite in your report; isn't that correct?
A. That's correct.
Q. And this study, in fact, has approximately nine additional studies that weren't included in the 2013 Cochrane view; isn't that correct?
MR. KOOPMANN: Object to form; asked and answered.
A. Yeah, that's correct.
Q. (By Mr. Bentley) Do you agree with the authors of the 2016 Cochrane review that concluded that permanent mesh implants such as Prolift are associated with a higher reoperation rate for stress urinary incontinence? Do you agree with that statement?

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A. I don't agree with the statement.
Q. And in your report, have you provided any type of analysis or reason as to why you disagree with that statement?
A. Yeah, I think I've stated to the contrary, from my review of other medical literature.
Q. Right. But in your report, you haven't explained why you disagree with the 2016 Cochrane review's conclusions that it's -- that mesh kits such as Prolift are associated with a higher reoperation rate for stress urinary incontinence; isn't that correct?
MR. KOOPMANN: Object to form.
A. That's correct.
Q. (By Mr. Bentley) Doctor, do you agree with the 2016 Cochrane author's conclusion that permanent mesh is associated with higher rates of reoperation for mesh exposure?
MR. KOOPMANN: Object to form.
A. Compared to what?
Q. (By Mr. Bentley) To nonpermanent mesh implants such as the --
A. Yes, I agree with that.
Q. Do you agree with the authors of the

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2016 Cochrane review -- do you agree with their conclusions that Prolift and permanent mesh kits are associated with a higher rate of bladder injury at surgery and de novo stress urinary incontinence?

A. When compared to native tissue repairs?

Q. Yes.

A. Yes.

Q. And the authors of the 2016 Cochrane review also conclude that the risk-benefit profile means that transvaginal mesh has limited utility in primary surgery. Do you agree with that statement?

A. No, I do not.

Q. But as you've previously testified, there's a narrower patient profile that you think is appropriate for using Prolift or Prolift+M as a primary surgery, right?

A. Yes.

Q. And I believe you testified that system reviews have a preset inclusion and exclusion criteria for which studies -- or how they're going to approach which studies to analyze; is that correct?

A. They should, yes.

Q. And you don't have a preset inclusion criteria for which studies you analyze in your

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report; isn't that correct?

A. I have criteria. I mentioned those criteria earlier.

Q. And what were the criteria -- strike that.

And do you have a preset exclusion criteria for which studies you didn't discuss in your report?

A. I have an inclusion criteria, I guess you can flip that and make it exclusion, but as I mentioned earlier, I look for studies that are well-designed of high levels of evidence, that are from reputable peer-reviewed journals, that have a large cohort of patients, preferably multi-center studies, et cetera.

Q. And did we discuss a couple of studies that you felt were reputable and important studies that could have met your inclusion criteria?

MR. KOOPMANN: Object to form.

A. We discussed studies that I didn't include in my report, yes.

Q. (By Mr. Bentley) Would they have met your inclusion criteria?

A. I would have to look at them more specifically. I didn't have time to look at those.

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They may have; they may not have.

Q. Doctor, we previously discussed that you hold a theory that mesh pain might be related to infection; is that correct?

A. It's one of possible many theories, yes.

Q. And my previous questions were, where in your report do you discuss this theory that the pain that many of these patients are suffering might be attributable to mesh-related infection? Do you discuss that anywhere in your report?

A. No.

Q. And that's not discussed in the IFU, right?

A. Infection's discussed in the IFU. Pain's discussed in the IFU.

Q. But the theory that the pain is being caused by a mesh-related infection, that's not discussed, right?

A. IFU's not going to discuss theories.

Q. It's not discussed in the IFU, right?

A. It's not discussed.

Q. Doctor, you testified about the 2011 Altman RCT earlier; do you remember that?

A. I do.

Q. And was that an important study to you?

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A. It was.

Q. Do you know if there were systematic problems with the POPQ measurements in that study?

A. I'd have to take a look at the study again if you want to go through that. I would be surprised to hear that.

Q. As you sit here today, you don't have any knowledge regarding that, though?

A. No.

Q. Do you know who Dr. Jeffrey Drazen is?

A. No, I do not.

Q. I'll represent to you that Dr. Drazen was the editor in chief of the New England Journal of Medicine and that he was deposed in the Ethicon litigation. Do you know if you've reviewed his deposition testimony?

A. No, I have not.

Q. So if I told you that he testified that there were issues with the POPQ measurements, you would have no information one way or the other if that was correct or not?

MR. KOOPMANN: Object to form; foundation.

A. As I mentioned earlier, I'd be surprised to hear that experienced surgeons would have problems measuring -- taking POPQ measurements.

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Q. (By Mr. Bentley) Would it affect your opinions on your evaluation of the reliableness of the Altman study if you learned that there were, indeed, problems with the measurements of the POPQ?
MR. KOOPMANN: Object to form.
A. Was he a reviewer of that article, or did he write a published editorial on that article?
Q. (By Mr. Bentley) I'm going to re-ask my question, Doctor.
If Dr. Drazen testified that there were, indeed, problems with the POPQ measurements in the Altman 2011 study, assuming that, would that affect your evaluation of whether or not that study was reliable?
A. No, it would not.
Q. You don't care if there were problems with the POPQ measurement in the study you relied upon?
A. The fact that Dr. Drazen has that opinion in his deposition doesn't make that statement true. That's his opinion. I don't believe that's the opinion of Dr. Altman and his coauthors, that they had problems measuring POPQ.
Q. And Doctor, you testified earlier about the Prolift Surgeon's Resource Monograph; do you

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remember that?
A. I do.
Q. And I believe you testified that the monograph contains some technical pearls; is that correct?
A. Technical pearls, that's correct.
Q. And what's the purpose of providing technical pearls to surgeons?
A. Technical pearls are to help newer surgeons gain insight that's only relevant after doing a certain number of cases. So it's a way of more experienced surgeons sharing information with others.
Q. And you believe that's helpful, right?
A. Yes, it's helpful.
Q. Do you have any legal basis for why Ethicon couldn't have included that information in the IFU procedural steps?
MR. KOOPMANN: Object to form.
A. This is a 25-page document that was collected years after Prolift was launched, and it's just a wealth of information on the experience. So there's no way this could have been included in the IFU at its onset. So I don't know how this could have been included in the IFU.

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Q. (By Mr. Bentley) And the initial IFU, you don't know how this could be included; is that your testimony?
A. That's my testimony, yes.
Q. But once the Prolift came to market and the information that's provided in this monograph was obtained, do you know of any reason why Ethicon couldn't have provided that information in an updated IFU?
A. I think they did a good job providing the information in the form of the Prolift monograph. That's more than what you would see with any other product like Elevate or Bard Avaulta. I've never seen anything like this monograph for any other mesh kit on the market, whether it's for prolapse or incontinence.
MR. BENTLEY: I'm going to strike as nonresponsive.
Q. (By Mr. Bentley) Doctor, my question is, is there any legal reason why Ethicon could not have updated the Prolift IFU with the technical pearls that are detailed in the Surgeon's Resource Monograph?
MR. KOOPMANN: Object to form; asked and answered.

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A. I'm not aware of any legal reasons, but I think there's a lot of practical reasons why it would not have been in an IFU.
MR. BENTLEY: I'm going to strike after "legal reasons."
Q. (By Mr. Bentley) Doctor, do you have any understanding as to whether every surgeon that implanted the Prolift received the monograph that you reviewed?
A. I don't have a way of knowing that, no.
Q. Is the monograph included with every Prolift or Prolift+M product as it's sold?
A. I don't know the answer to that.
Q. But the IFU you know is provided with the Prolift or Prolift+M with every product sold, right?
A. The IFU, yes.
MR. BENTLEY: I have no further questions. Thank you.
MR. KOOPMANN: Just a couple follow-ups, Dr. Flynn.
EXAMINATION
BY MR. KOOPMANN:
Q. Do you think there's a surgeon in America who is unaware that an infection can cause

pain?
MR. BENTLEY: Objection; speculation, form and foundation, asked and answered.
A. No.
Q. (By Mr. Koopmann) If somebody cuts their finger and that cut, that little cut on their finger gets infected, will that cause pain?
MR. BENTLEY: Objection; argumentative.
A. Yes.
MR. BENTLEY: Form.
Q. (By Mr. Koopmann) Did you ever hear of the Altman 2011 RCT being retracted by the New England Journal of Medicine?
A. No.
Q. Is that something that happens from time to time with an article if there's some significant problem with an article?
MR. BENTLEY: Objection; form and foundation, speculation, vague.
A. Yes, it does happen. I've seen articles be retracted from the literature when new information's been discovered.
MR. KOOPMANN: No further questions.
(Discussion held off the record.)
EXAMINATION

BY MR. BENTLEY:
Q. Doctor, I'm handing you what's titled "Expert Report Re: Gynecare Prolift Pelvic Floor Repair System." It's a report dated February 26, 2016, and it appears to have your signature on this last page. Does that look like your report entered in this litigation?
A. Yes, it does.
Q. And I'm handing you a similar report titled "Prolift+M." Does that look like your report regarding the Prolift+M products in this litigation?
A. It does.
MR. BENTLEY: Thank you.
MR. KOOPMANN: Are you going to mark those as exhibits?
MR. BENTLEY: Please mark those as 11 and 12. Prolift will be 11, +M will be 12.
(Exhibits 11 and 12 were marked for identification.)
(Whereupon, the deposition was concluded at 5:50 p.m. on April 14, 2016.)

I, BRIAN FLYNN, M.D., do hereby certify that I have read the foregoing transcript and that the same and accompanying amendment sheets, if any, constitute a true and complete record of my testimony.

_____
Signature of Deponent

( ) No Amendments
( ) Amendments Attached
Subscribed and sworn to before me this _____ day of _____, 2016.

Notary Public: _____
Address: _____
_____
My commission expires: _____
Seal:

MLG

REPORTER'S CERTIFICATE

STATE OF COLORADO)
) ss.
COUNTY OF DENVER)

I, MELANIE L. GIAMARCO, do hereby certify that I am a Registered Professional Reporter and Notary Public within the State of Colorado; that previous to the commencement of the examination, the deponent was duly sworn by me.
I further certify that this deposition was taken in machine shorthand by me at the time and place herein set forth, that it was thereafter reduced to typewritten form, and that the foregoing constitutes a true and correct transcript of the proceedings had.
I further certify that I am not employed by, related to, nor of counsel for any of the parties herein, nor otherwise interested in the result of the within litigation.
In witness whereof, I have affixed my signature and seal this 18th day of April, 2016.

Melanie L. Giamarco
Registered Professional Reporter
Registered Merit Reporter
Certified Realtime Reporter
My commission expires: August 25, 2017.